Time And Study Collection System (TASCS)

USER GUIDE

Clinical Research Budgeting/Billing System and Process

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Section I - The Process

BACKGROUND

Clinical research is a fundamental and critically important component of any Academic Health Center's mission. It is also an activity that is highly regulated, deeply complex and thus, carries an inherent risk.

Locally, as well as nationally, there has been a lack of communication intra- and inter-organizationally regarding clinical research processes. Clinical trial budgeting and billing is one of those processes that has become an identified risk area. Historically, there have been very few, or no, policies and processes defining or guiding this activity.

The University's Academic Health Center, UMPhysicians and Fairview Health Services have collaborated to create organizational policies in order to address clinical research budgeting and billing.

The goal in creating policies is to foster compliant clinical research budgeting and billing across our organizations. Elements of a successful program include the following:

- Define payers for protocol services prospectively
- Integrate language and practice – consent form, clinical trial agreement, billing practice
- Identify research participants within the Providers' systems
- Identify research related services at point of care – assign to correct payers
- Correctly code claims

A process diagram has been crafted to demonstrate the steps involved in implementing the budgeting and billing policy. The process diagram can be found in the Roles and Responsibilities section that follows.

The AHC Database (TASCS) is a central tool developed to help support and manage the process.

APPLICABLE CLINICAL RESEARCH

The AHC policy states that clinical research meeting the following definition must be entered into TASCS.

Clinical research is defined as a systematic investigation, including research development, testing and evaluation involving human subjects, their data, records or tissue and is designed to develop or contribute to generalizable knowledge. Clinical research meeting the Institutional Review Board (IRB) criteria for exemption (per 45 CFR 46.101) does not have to be entered into the AHC database.

NOTE: *At this time, only research involving the use of Fairview or UMPhysicians services must be entered into the AHC database.*

Humanitarian Use Device (HUD)/Humanitarian Device Exemptions (HDE)

According to federal definition (21 CFR 814), HUDs/HDEs are not clinical research. However, the same regulation also requires IRB approval to use these devices and Medicare regulations require that the HDE number appear on any submitted claims. Therefore, information related to the use of HUDs/HDEs must also be entered into the AHC database.

ROLES AND RESPONSIBILITIES

Managing clinical research is a complex process requiring communication between individuals and across organizations. Defining roles and responsibilities will lend clarity and improve efficiencies in the overall research process.

Every project entered into TASCS has three roles identified: Investigator, Protocol Contact and Billing Contact. Communication about each project includes one or more of the individuals in the identified roles. The following are suggested responsibilities related to using TASCS - categorized by role.

Investigator

The Investigator enters clinical research information for each clinical research protocol into TASCS or may delegate this function. The Investigator prints a copy of the billing grid report, signs it, and submits it with the initial IRB application. TASCS must be updated within 72 hours of the following events:

- each subject/participant who signs an initial consent form,
- each subject/participant visit that occurs, and
- each subject/participant who ends participation in the clinical research.

Protocol Contact/Research Coordinator

If delegated to the Protocol Contact/Research Coordinator by the Investigator, enters clinical research information for each protocol into TASCS. The Protocol Contact prints a copy of the billing grid report, obtains principal Investigator's signature, and submits signed billing plan with the initial IRB application. TASCS must be updated within 72 hours of the following events:

- each subject/participant who signs an initial consent form,
- each subject/participant visit that occurs, and
- each subject/participant who ends participation in the clinical research.

Billing Contact/Administrator

The Billing Contact assists with purchase order preparation based on the budget. Monitors and reviews reports in TASCS as a tool to assist ongoing account management.

Service Providers

Service Providers, in this context, are employees of University of Minnesota Physicians or Fairview Research Administration. Service Providers will assist Investigators in determining whether or not the clinical research protocol meets criteria for a Qualifying Clinical Trial under Medicare's policy. They will continue to provide research prices and set up research billing accounts. Providers will establish a process to identify research

participants in applicable systems and use TASCS information to help ensure charges are on the correct billing accounts. They will also facilitate research coding on claims.

TASCS Support

TASCS Support designs, plans, and coordinates end-user TASCS training and provides assistance to end-users including assistance with data entry when necessary. This role serves as the TASCS Support and a liaison between Users, Providers and TASCS Programmers.

Academic Health Center (AHC) Information Systems (IS)

AHC IS writes and maintains code for the web application. They resolve technical barriers and end-user concerns, as appropriate. IS participates in the development of reports for various stakeholders including end-users and service Providers and in the development of policies, procedures, and standards for ensuring the integrity of the database.

Institutional Review Board (IRB)

The IRB serves as a checkpoint to help assure congruent language and practice in the research consent process. They review language in the consent form regarding cost to the participant and match information to the signed billing grid report. The IRB notifies the principal Investigator when discrepancies are identified. Final IRB approval is not granted until discrepancies are resolved.

Sponsored Protocols Administration (SPA)

Facilitates compliance with internal and external requirements. Reviews the contract language and proposed budget for conformity with Regents' policies. Negotiates and executes the clinical trial agreement on behalf of the Regents. Provides Notice of Grant Award to principal investigator and designated departmental staff. Emails NOGA notification to Fairview Research Administration Office.

Assistant Vice President for Research – Academic Health Center

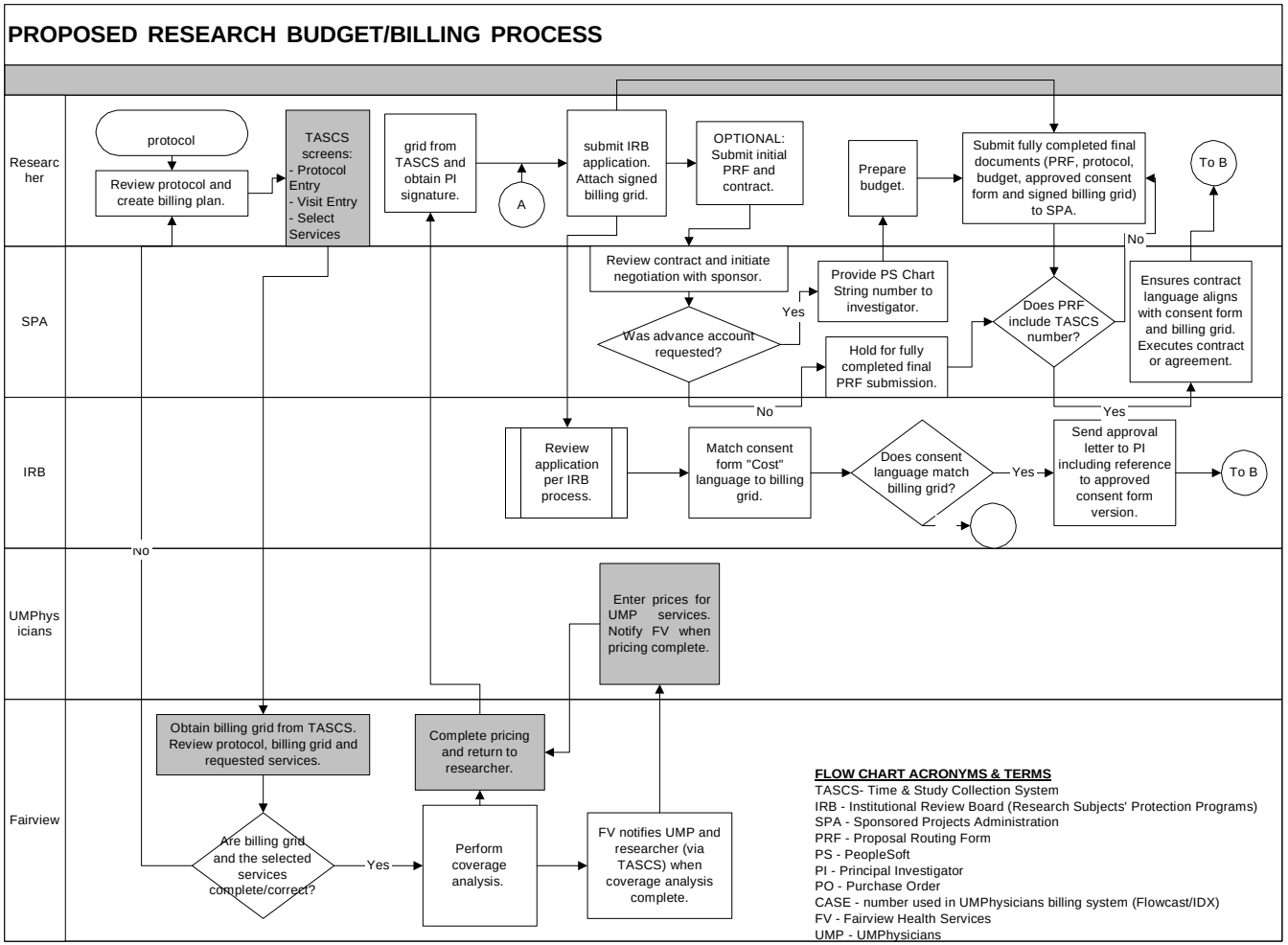
This individual is the policy owner at the AHC and is responsible for compliance.

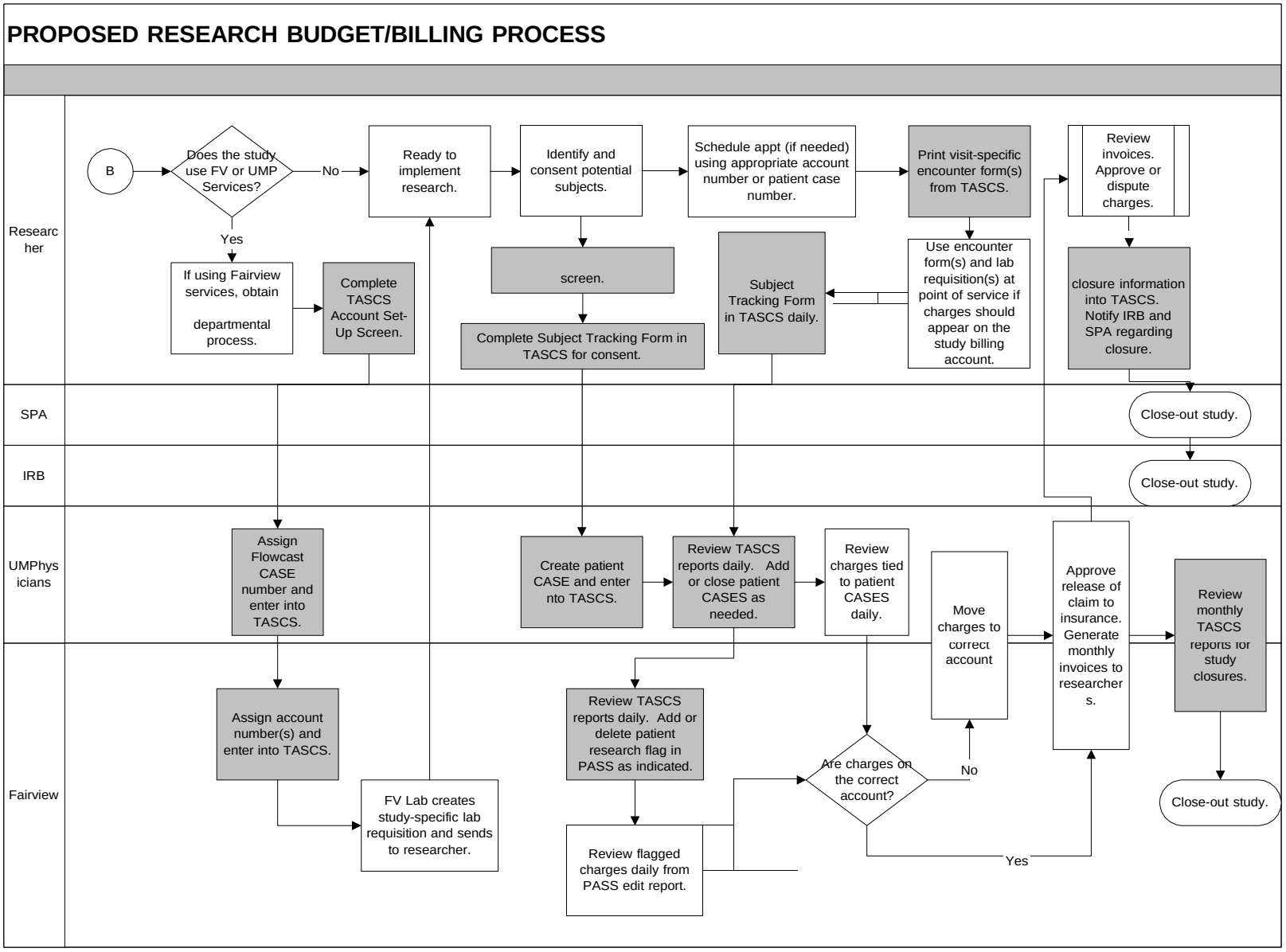
Research Integrity and Oversight Programs (RIOP)

This office assists in managing compliance with TASCS policy and procedures.

RESEARCH PROCESS FLOW

The success of the process is dependent upon a range of stakeholders including the researchers, the IRB, SPA and the Providers. A detailed process map is provided below on the next two pages. The shaded steps denote user interaction with TASCS.


PROPOSED RESEARCH BUDGET/BILLING PROCESS
Researcher
SPA
IRB
UMPhysicians
Fairview
protocol
Review protocol and create billing plan.
TASCS screens: - Protocol Entry - Visit Entry - Select Services
grid from TASCS and obtain PI signature.
A
submit IRB application. Attach signed billing grid.
OPTIONAL: Submit initial PRF and contract.
Prepare budget.
Submit fully completed final documents (PRF, protocol, budget, approved consent form and signed billing grid) to SPA.
To B
No
Review contract and initiate negotiation with sponsor.
Was advance account requested?
Yes
Provide PS Chart String number to investigator.
Hold for fully completed final PRF submission.
No
Does PRF include TASCS number?
Yes
Ensures contract language aligns with consent form and billing grid. Executes contract or agreement.
Review application per IRB process.
Match consent form "Cost" language to billing grid.
Does consent language match billing grid?
Yes
Send approval letter to PI including reference to approved consent form version.
To B
No
Enter prices for UMP services. Notify FV when pricing complete.
Obtain billing grid from TASCS. Review protocol, billing grid and requested services.
Complete pricing and return to researcher.
Are billing grid and the selected services complete/correct?
Yes
Perform coverage analysis.
FV notifies UMP and researcher (via TASCS) when coverage analysis complete.
FLOW CHART ACRONYMS & TERMS
TASCS- Time & Study Collection System
IRB - Institutional Review Board (Research Subjects' Protection Programs)
SPA - Sponsored Projects Administration
PRF - Proposal Routing Form
PS - PeopleSoft
PI - Principal Investigator
PO - Purchase Order
CASE - number used in UMPhysicians billing system (Flowcast/IDX)
FV - Fairview Health Services
UMP - UMPhysicians


PROPOSED RESEARCH BUDGET/BILLING PROCESS
Researcher
SPA
IRB
UMPhysicians
Fairview
B
Does the study use FV or UMP Services?
No
Yes
Ready to implement research.
Identify and consent potential subjects.
Schedule appt (if needed) using appropriate account number or patient case number.
Print visit-specific encounter form(s) from TASCS.
Review invoices. Approve or dispute charges.
If using Fairview services, obtain departmental process.
Complete TASCS Account Set-Up Screen.
screen.
Complete Subject Tracking Form in TASCS for consent.
Subject Tracking Form in TASCS daily.
Use encounter form(s) and lab requisition(s) at point of service if charges should appear on the study billing account.
closure information into TASCS. Notify IRB and SPA regarding closure.
Close-out study.
Close-out study.
Assign Flowcast CASE number and enter into TASCS.
Create patient CASE and enter nto TASCS.
Review TASCS reports daily. Add or close patient CASES as needed.
Review charges tied to patient CASES daily.
Move charges to correct account
Approve release of claim to insurance. Generate monthly invoices to researchers.
Review monthly TASCS reports for study closures.
Assign account number(s) and enter into TASCS.
FV Lab creates study-specific lab requisition and sends to researcher.
Review TASCS reports daily. Add or delete patient research flag in PASS as indicated.
Review flagged charges daily from PASS edit report.
Are charges on the correct account?
No
Yes
Close-out study.

COMPLIANCE

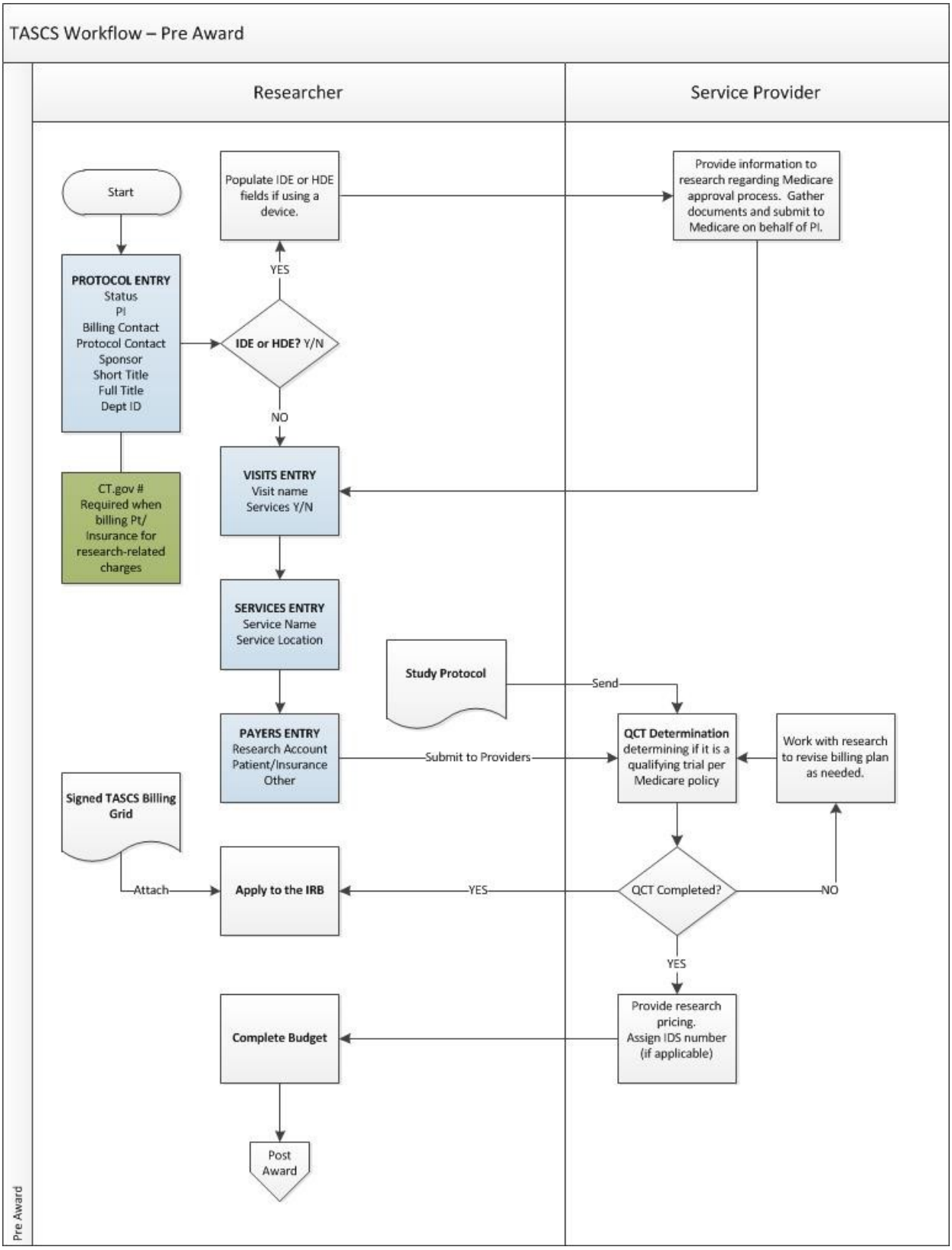
Institutional policies (see Appendix F) describe the rationale and procedures for compliant budgeting and billing practices within the AHC, UMPhysicians and Fairview Health Services. As discussed earlier, this is a heavily regulated activity and is viewed as a high-risk area. Compliance is monitored and reported to Senior Leadership at the AHC, UMPhysicians and Fairview Health Services.

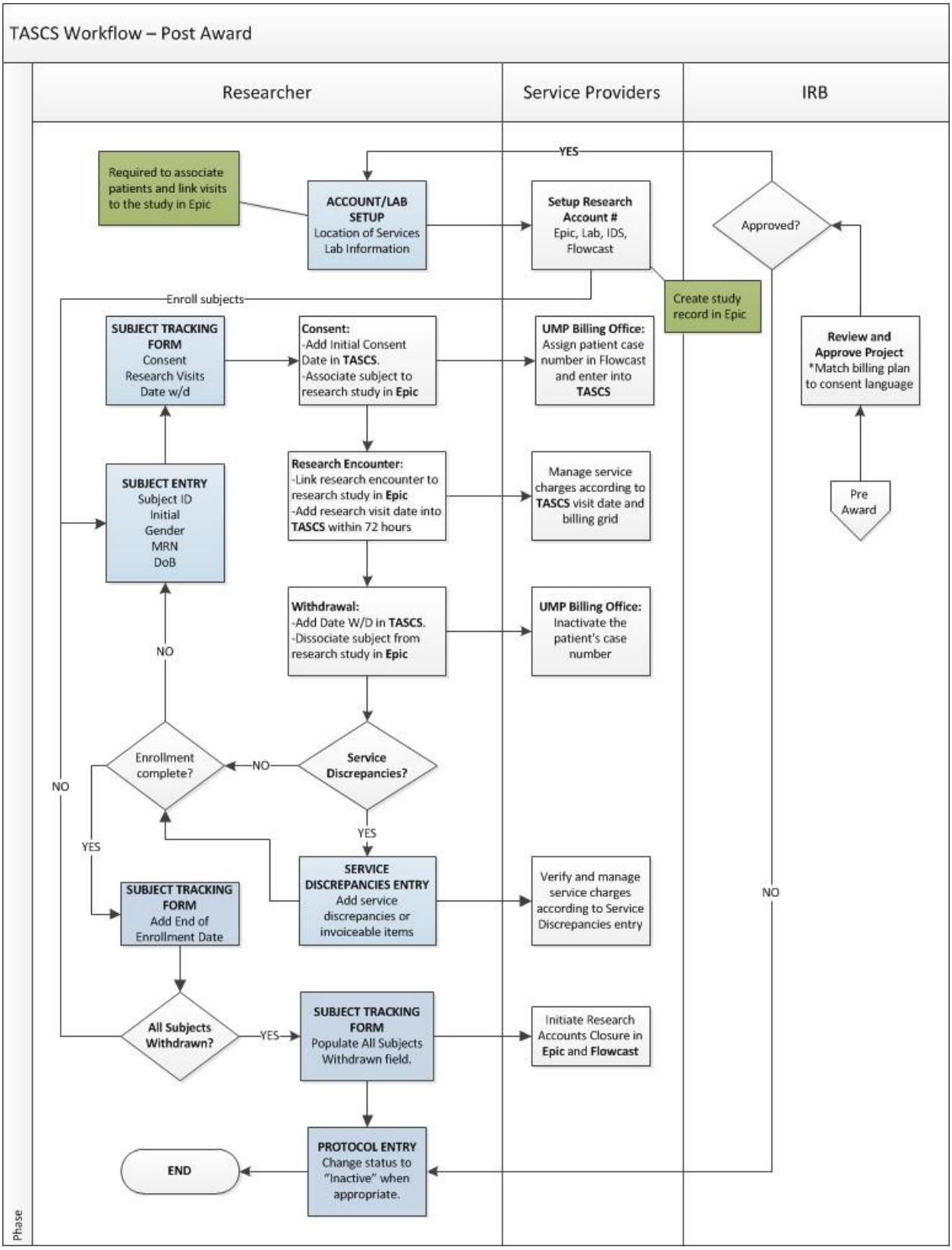
The driving principle used to facilitate compliance is to assist all stakeholders in understanding and adhering to the defined processes. Resources are available to assist Users:

- Classroom and individualized training
- TASCS User Manual
- TASCS Support

Processes have been developed to monitor adherence to the policy. Routine reports identifying compliance concerns are reviewed by TASCS Management. Users are notified about potential compliance concerns and asked to respond. Non-response to TASCS Management's notification or issues that can't be addressed by this process are forwarded to the Office of Regulatory Affairs for resolution.

TASCS Workflow




TASCS Workflow – Post Award
Researcher
Service Providers
IRB
Required to associate patients and link visits to the study in Epic
ACCOUNT/LAB SETUP
Location of Services
Lab Information
YES
Setup Research Account #
Epic, Lab, IDS, Flowcast
Approved?
Create study record in Epic
Enroll subjects
SUBJECT TRACKING FORM
Consent
Research Visits
Date w/d
Consent:
-Add Initial Consent Date in TASCS.
-Associate subject to research study in Epic
UMP Billing Office:
Assign patient case number in Flowcast and enter into TASCS
Review and Approve Project
*Match billing plan to consent language
Pre Award
SUBJECT ENTRY
Subject ID
Initial
Gender
MRN
DoB
Research Encounter:
-Link research encounter to research study in Epic
-Add research visit date into TASCS within 72 hours
Manage service charges according to TASCS visit date and billing grid
Withdrawal:
-Add Date W/D in TASCS.
-Dissociate subject from research study in Epic
UMP Billing Office:
Inactivate the patient's case number
NO
Enrollment complete?
NO
Service Discrepancies?
YES
NO
YES
SUBJECT TRACKING FORM
Add End of Enrollment Date
SERVICE DISCREPANCIES ENTRY
Add service discrepancies or invoiceable items
Verify and manage service charges according to Service Discrepancies entry
NO
All Subjects Withdrawn?
YES
SUBJECT TRACKING FORM
Populate All Subjects Withdrawn field.
Initiate Research Accounts Closure in Epic and Flowcast
PROTOCOL ENTRY
Change status to "Inactive" when appropriate.
END
Phase

Section II - Using TASCS

GENERAL INFORMATION

Access and Security

Before access to TASCS is granted, each prospective user must complete training and submit a TASCS Access Request form. Information regarding TASCS training dates and registration are available on the CTSI website (http://www.ctsi.umn.edu/sites/default/files/TASCS-training.pdf), on the TASCS website via the Links menu, or by contacting TASCS Support (tascs@umn.edu).

The TASCS Access Request Form is found in Appendix B and is also available digitally, via the CTSI website: http://www.ctsi.umn.edu/researcher-resources/forms-and-templates.

Researchers and research staff will be asked if they should be assigned to one or more of the following roles: Investigator, Protocol Contact and/or Billing Contact. Individuals may select all three if they choose.

Service Providers, IRB, SPA and RIOP users should indicate their affiliation on the TASCS Access Application Form.

The access application options are:

A. Complete, scan (if printed), and e-mail the Access form to TASCS Support (tascs@umn.edu)

   Except for Investigators, a supervisor's signature is required. The supervisor should forward the approved Access form to the TASCS Web Application Specialist.

B. Complete and fax the Access form to (612) 625-2695.

C. You may also choose to complete, print, and then send the Access form via intercampus mail to:

TASCS Support Mail Code 1932 717 Delaware Street SE Minneapolis MN 55414

If you have any questions about how to complete the TASCS Access Application Form please call TASCS Support (tascs@umn.edu) at 612-624-4612.

Applications will be processed as soon as possible, usually within one business day of receipt. Applicants will receive an e-mail notice that access has been granted.

TASCS maintains an audit trail and will record the "who, when and what" regarding data changes made to any field in the system. Please be careful when viewing TASCS screens.

TASCS access will be granted based on DeptID. Careful completion of the DeptID section of the TASCS Access Application form will insure access to the information users need. DeptIDs can be added and deleted as needed for each user.

Exceptions to DeptID access include:

- Cancer Center Clinical Trials Office - access granted based on populated CPRC Number field.

Please be aware that all protocols with information in the "CPRC number" field will be available to personnel in the Cancer Center Clinical Trials Office.

- Clinical and Translational Sciences Institute (CTSI) - access granted based on protocols entered by CTSI
- Institutional Review Board - read only access to the Protocol screens; no access to Visits, Services, Payers or Subject Tracking screens. Can view all standard reports except the researcher's version of the Subject Tracking Form Report
- Sponsored Projects Administration - same access as the IRB
- Research Integrity and Oversight Programs (RIOP) – read only access to all
- Service Providers - access to all

Logging into TASCS

The web address for TASCS is: **https://secure.ahc.umn.edu/tascs**

The log in screen defaults to the University x500 ID validation screen.

- University employees: University employees will use this screen with their x500 ID and password to log into TASCS.

- Non-university employees (or those without an "x500 ID): You will need to establish a User Account with the University before TASCS can assign a log-in for you.

  Contact TASCS Support for assistance.

  University guest accounts can be registered here: https://www.umn.edu/dirtools/guestportal. Send the new User information to TASCS Support (tascs@umn.edu) and request TASCS access.

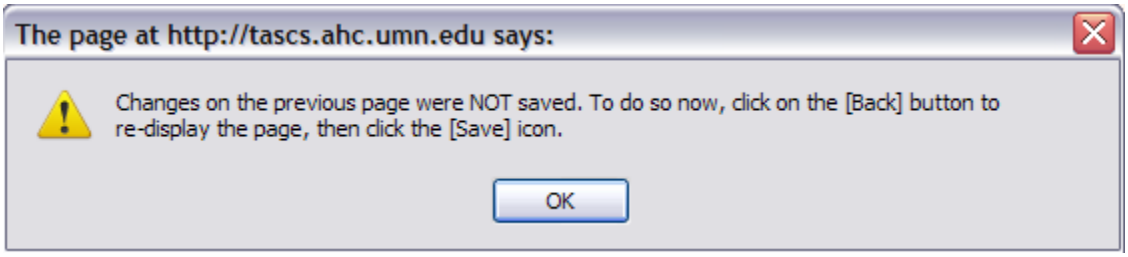
Enter your ID and password in the designated fields and click on the "Login" button to the right. If you forget your password, click on the "Forgot your password?" link for help.

Saving and Timing Out

TASCS will prompt the user to save work before exiting screens. Some screens allow two options – "Save" and "Save/Submit". Users should choose "Save" while still working on the entry screen. Once a screen is complete, choose "Save/Submit". Selecting this option will send e-mail notification to service Providers that your request is ready for processing.

While TASCS allows some amount of time before timing out, users are encouraged to save work frequently and whenever data entry in TASCS is interrupted.

When attempting to close a TASCS entry screen before saving, the following message will appear:


The page at http://tascs.ahc.umn.edu says:
Changes on the previous page were NOT saved. To do so now, click on the [Back] button to re-display the page, then click the [Save] icon.
OK

Searching

When choosing any options in the Edit menu, you'll be presented with a search screen. You can search for studies using any one of the criteria. Use more than one criterion to further narrow the search.

- **TASCS ID:** search for the study by its unique identifier in TASCS
- **Protocol Short Name:** search for the study using a key-word in the Short Protocol Title
- **PI:** search for the study using the last name of the PI
- **Protocol Contact:** search for the study using the last name of the protocol contact.
- **Sponsor:** search for the study using the sponsor's name
- **Deptid:** search for the study using the Dept ID

The search may result in more than one study.

Example:

PI = doe
Sponsor = inter

This search will find all studies where the PI's last name starts with "doe" AND where the sponsor's name starts with "inter". The result lists all of John Doe's studies sponsored by Intermune.

Navigation Tips

The following navigation tips are not necessary, but are offered as useful options when entering information in TASCS:

Keyboard Keys	Description
Alt + Left Arrow	Back a page.
Alt + Right Arrow	Forward a page.
ALT + D	Select the address bar so you can enter a new URL
HOME	Brings you to the top of the page
END	Brings you to the bottom of the page
TAB	Skip to the next field
SHIFT + TAB	Skip to the last field
CTRL + A	Select all
CTRL + C	Copy
CTRL + V	Paste

Getting Started

It is important to guard against the duplicate entry of protocols in TASCS. Researchers can check a list of protocols already entered in TASCS by going to the Edit menu and choosing Protocol. Searching by PI will yield the list of protocol short titles, sponsors, etc. that will help users determine whether or not the protocol might already be entered. Whenever there is a question – the user should check before entering a new protocol.

It is recommended that the primary Protocol Contact for a protocol be responsible for setting up new protocols in TASCS – but researchers and departments can determine how to best assign responsibilities. TASCS Support will, on a regular basis, search for duplicate entries and work with Protocol Contacts to correct any multiple entries of protocols in TASCS.

Researcher Responsibilities

Adding a new Sponsor, Principal Investigator, Billing Contact or Protocol Contact.

Every effort will be made to prevent duplicate entries of sponsors, and persons (including Investigators, Billing Contacts, Protocol Contacts, etc.) in TASCS.

When entering a new protocol in TASCS, if the Sponsor or Person is not listed as a current drop down option, TASCS Support will enter the new Sponsor or Person into TASCS. When a sponsor, Investigator, Billing Contact or Protocol Contact must be added – the user should e-mail or fax the required new information to:

Email	Fax	Phone
tascs@umn.edu	612.625.2695	612.626.4612

Information needed to enter a new Sponsor or new Person in TASCS can be found in Appendix B.

It is important to note that every Sponsor entered in TASCS has a funding source associated with that Sponsor. The selection of the appropriate funding source has implications for assuring the proper rates for research services are applied. If you have questions about the funding source associated with a Sponsor please contact TASCS Support. For more information about funding sources please see the Sponsor request form in Appendix B.

The IRB will review a budgeting/billing grid as part of all new protocol applications received after September 1, 2008. To prepare a budgeting/billing grid, follow the steps described in the next sections.

You can request research prices from Fairview and UMPhysicians in order to help determine study feasibility for grant submissions. See "Pricing Only" information in the" How To" section of this manual

TASCS requirements are organized into activities that occur before subjects are enrolled and activities that between subject enrollment and study closure

The following information describes the data entry and communication process from beginning to end. Sections of the process are divided between Researcher Responsibilities (most commonly meaning either Investigator or Protocol Contact responsibilities) and Service Provider (meaning UMP or Fairview) responsibilities. A complete list of all TASCS entry screen fields can be found in Appendix E.

Prior to Subject Enrollment

This section includes data entry and communication processes from the point of study concept through study initiation. The following TASCS screens are described in this section:

- Protocol
- Visits
- Services
- Payers
- Pricing
- Account Lab/Set-up

Step 1 - Protocol Entry Screen

Required Information for Step 1

Status
Principal Investigator
Billing Contact
Protocol Contact
Sponsor
Short Protocol Title
Full Protocol Title
Dept ID

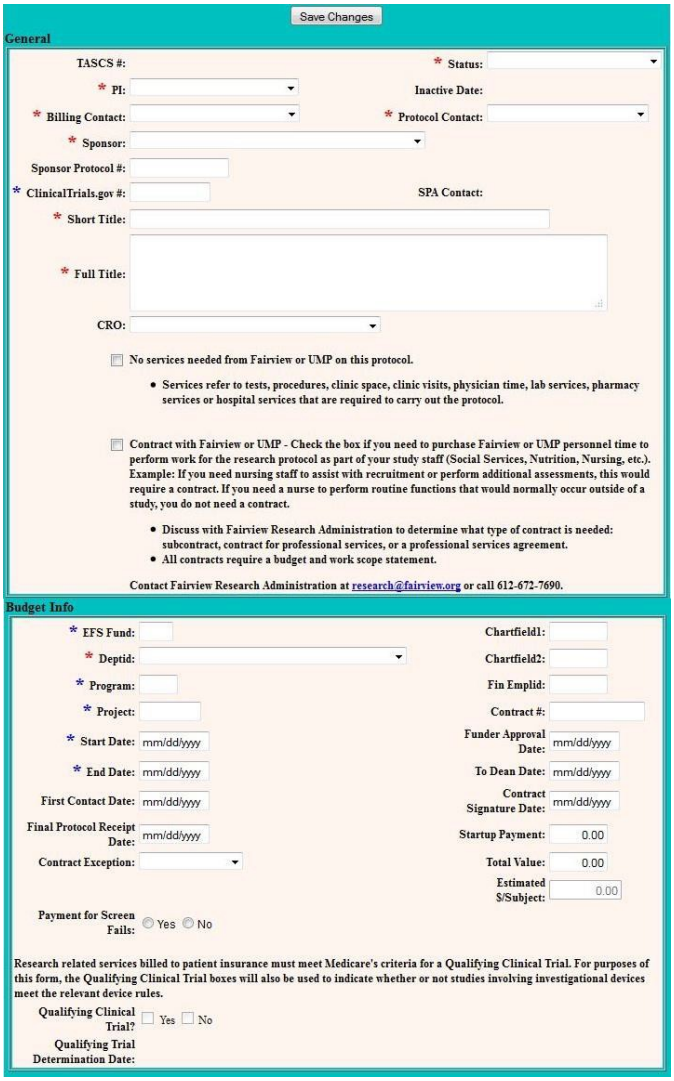
1. Go to the “New” menu and choose “Protocol”.

2. Enter the required information.
   - Fields with red asterisks are required in order to save.
   - Fields with blue asterisks must be updated as the information becomes available
   - Fields with no asterisks are optional and available as desired.

3. Save Changes.

4. Write down the TASCS ID for reference.

❖ The field definitions for the Protocol screen can be found in Appendix E.


Save Changes
General
TASCS #:
* Status:
* PI:
Inactive Date:
* Billing Contact:
* Protocol Contact:
* Sponsor:
Sponsor Protocol #:
* ClinicalTrials.gov #:
SPA Contact:
* Short Title:
* Full Title:
CRO:
No services needed from Fairview or UMP on this protocol.
Services refer to tests, procedures, clinic space, clinic visits, physician time, lab services, pharmacy services or hospital services that are required to carry out the protocol.
Contract with Fairview or UMP - Check the box if you need to purchase Fairview or UMP personnel time to perform work for the research protocol as part of your study staff (Social Services, Nutrition, Nursing, etc.). Example: If you need nursing staff to assist with recruitment or perform additional assessments, this would require a contract. If you need a nurse to perform routine functions that would normally occur outside of a study, you do not need a contract.
Discuss with Fairview Research Administration to determine what type of contract is needed: subcontract, contract for professional services, or a professional services agreement.
All contracts require a budget and work scope statement.
Contact Fairview Research Administration at research@fairview.org or call 612-672-7690.
Budget Info
* EFS Fund:
Chartfield1:
* Deptid:
Chartfield2:
* Program:
Fin Emplid:
* Project:
Contract #:
* Start Date: mm/dd/yyyy
Funder Approval Date: mm/dd/yyyy
* End Date: mm/dd/yyyy
To Dean Date: mm/dd/yyyy
First Contact Date: mm/dd/yyyy
Contract Signature Date: mm/dd/yyyy
Final Protocol Receipt Date: mm/dd/yyyy
Startup Payment: 0.00
Contract Exception:
Total Value: 0.00
Estimated $/Subject: 0.00
Payment for Screen Fails: Yes No
Research related services billed to patient insurance must meet Medicare's criteria for a Qualifying Clinical Trial. For purposes of this form, the Qualifying Clinical Trial boxes will also be used to indicate whether or not studies involving investigational devices meet the relevant device rules.
Qualifying Clinical Trial? Yes No
Qualifying Trial Determination Date:

ClinicalTrials.gov

ClinicalTrial.gov # is required of Service Provider when charges are billed Insurance. Effective 1/01/2014.

Cancer Research

All protocols related to cancer must have a CPRC number entered on the Protocol screen in TASCS. If you have not yet been assigned a CPRC number – enter a placeholder in the CPRC “Number” field. **When your number is assigned – replace the placeholder number you entered.**

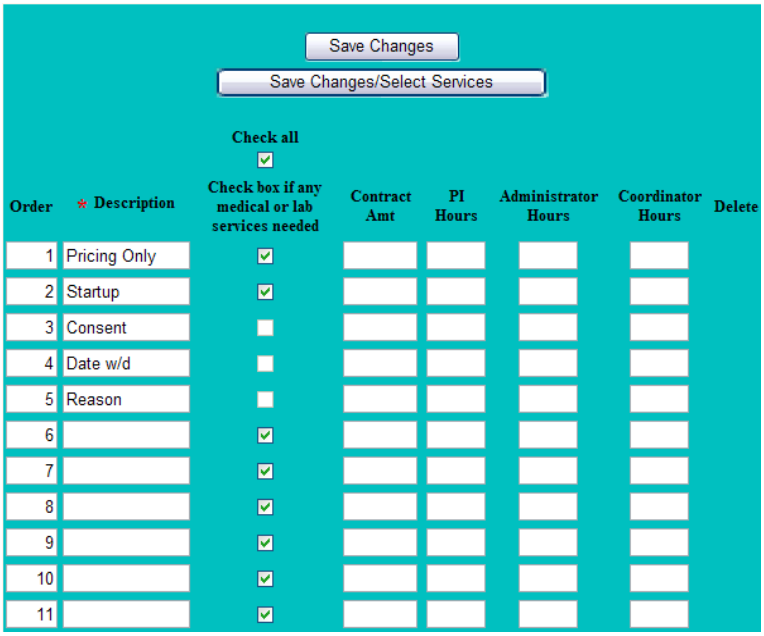
Question	Response
How should multiple sponsors be attached to a single protocol?	TASCS lets you indicate one sponsor in the system. • If the protocol is Investigator-initiated, choose "Investigator-initiated" with the appropriate funding source in parenthesis. • If any of the sponsors is a governmental department or agency, list that sponsor in the sponsor field. • If the study sponsor is a non-profit entity (University, foundation, etc.) and there is no governmental sponsor, list the non-profit entity in the sponsor field. • If all the sponsors are commercial (a business or industry), pick one to list in the sponsor field. In all instances, you may provide the names of other sponsors in the comment section, but they are not required.
Which sponsor should be chosen in TASCS when the study is Investigator-initiated, but funding is provided by a commercial source (business or industry)?	Choose "Investigator-initiated (B&I)" from the sponsor drop down list. You can identify the commercial sponsor's name in the comment field if you like, but it is not required.
How do you enter a single IRB protocol into TASCS when the protocol has multiple funding sources and titles? Currently, the study has separate account numbers based on title and funding source.	For projects such as these we'll have to use the EFS account string as the unique identifier rather than the IRB number. Each EFS account string will require its own Protocol entry into TASCS. Work with your department accountant.

Step 2 - Visit Entry Screen

Required Information for Step 2

Visit Description
Are Medical/Lab Services Needed?

1. To view the Visit screen either:
   - Click the Visits hyperlink near the top of the page, or
   - Go to the "Edit" menu and choose "Visits". Then search by TASCS number (or any search term of your choosing) for the Visits screen and choose "Search."



All data collection time points must be defined and entered as **uniquely named** visits in TASCS. Visits should be defined based on the protocol time points at which research data will be collected for each subject. Five visit descriptions (pricing only, startup, consent, date withdrawn, and a reason for the subject withdrawal) are auto-filled by TASCS. (The startup visit description is available for business use outside of the budgeting/billing policy but may be used to store optional information about startup activity.)

All other visits can be named at the user's discretion. Common labels include numbering visits such as Visit 1, Visit 2, etc. Other possibilities include Day 1, Day 7, Day 14, etc. Visits should include a number, and be identified in the way that will make information most useful to the researcher.

Check the box for each visit at which any medical or laboratory services will be needed. Medical or lab services refers to:

- Medical services
- Lab services
- Tests or procedures
- Use of clinic space or hospitalization
- Physician time

- Pharmacy services

The use of the above services must be entered into TASCS whether or not they are provided by Fairview or UMPhysicians.

When all available lines have been used – click on “Save Changes” and ten more blank lines will be made available. If you discover, after naming visits, that you must add a visit that would occur between visits already named, name a new visit on a blank line and use the Order column to indicate in what order the visit should occur. When you select “Save” TASCS will re-order the visits.

Remember to Save whenever your work is interrupted. Do not select “Save Changes/Select Services” until all of your visit descriptions have been entered. If you accidentally choose “Save Changes/Select Services” button and you are not finished entering visits, click the Visits link to return to the page or choose “Edit” Visits to continue.

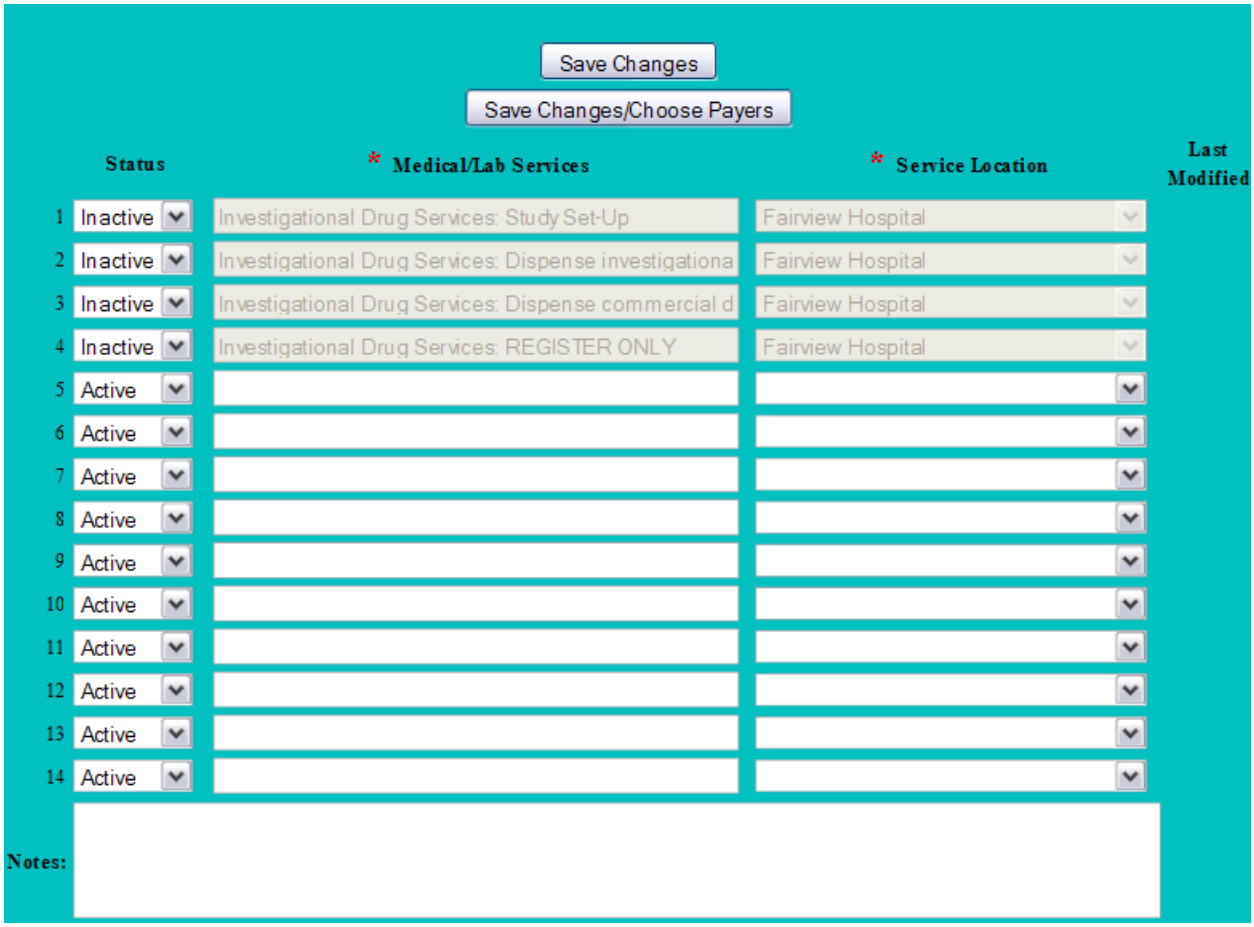
To delete visits from the Visit Entry screen check the box at the end of each Visit row. ***TASCS will not allow you to delete a visit if there is data stored (payers or subject tracking) for the visit you wish to delete.***

When all visits have been named, choose “Save Changes/Select Services”. The Services screen will appear.

Step 3 - Services Entry Screen

Required Information for Step 3

Medical / Lab Services
Service Location



Researchers are asked to enter medical and laboratory services – one line for each service location. What this means is that if the protocol will require imaging (MRIs, for instance) at both a Fairview facility and at the UMP Imaging Center – MRIs must be listed twice on the Services screen.

Enter the name of each test or procedure using the clearest and most specific terms possible to indicate the service needed. For instance, if the MRIs required by the protocol will require the use of a contrast agent, enter “MRI with contrast”. Service Providers will communicate with the Protocol Contact entered in TASCS whenever more information is needed to make sure TASCS reflects what the protocol requires.

All medical or laboratory services (tests, procedures, clinic space, clinic visits, physician time, lab services, pharmacy services, or hospital services that are required to carry out the protocol must be entered on the Services screen whether they will be provided by Fairview/University of Minnesota Physicians or not.

Status

The first column on this screen displays a "Status" dropdown field. TASCS will show each service (line) as active. You may change the status to inactive for those services that do not apply.

Services

Four lines related to Investigational Drug Services (IDS) will be auto-filled by TASCS on the Services screen. The service location for IDS services will also be auto-filled.

Location

After naming the test/procedure, the next field to enter will be to select the service location from the drop down. The Service Location drop down includes:

- UMMC Clinic
- UMP Clinic
- Fairview Clinic (Includes Maple Grove)
- Fairview Hospital
- UMP Imaging Center
- Other

Additional information on categorizing or understanding service locations is available in Appendix C.

If the Outpatient Laboratory (first floor PWB) or a hospital laboratory will be used – choose Fairview Hospital as the location.
If clinic laboratory services will be used – choose the appropriate clinic location.

If, for example, the protocol will require EKGs to be performed by the Outpatient Laboratory, enter "EKG (Lab) and choose Fairview Hospital as the location.

If the protocol includes services that may be incidental or required only under specific circumstances ("invoiceable"), use the Pricing Only procedure. This will allow Providers to provide a price for the services.

Last Modified

This column is auto-populated by TASCS.

Comments

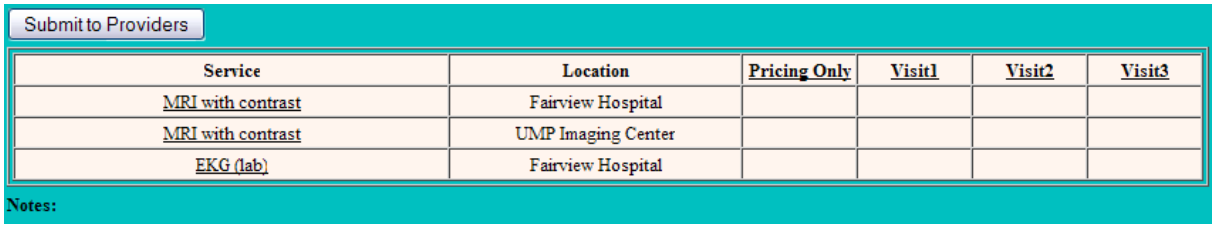
The Comment field is available to all users and is a free text field. Use this field as you wish to record details about the protocol, provide notes for Providers and other users, or store helpful information.

When you have completed the Services screen, click on the "Save Changes/Choose Payers" button and TASCS will bring you to the Payers screen. *You may also go to the "Edit" menu and choose "Payers". Then search by TASCS number (or any search term of your choosing) and choose "Search" to open the Payers screen.*

Step 4 – Payers Entry Screen

Required Information for Step 4

For each service listed, a payer must be identified at one or more visits.



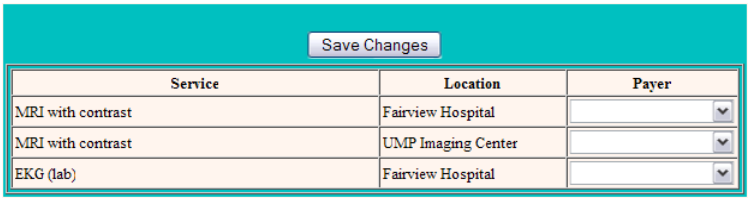
*Your screen may look different

Your visits and services appear in a table for you to populate the payer information. Payer information is the billing plan indicating who should pay for each service at specified visits. In some studies, a service might be appropriately billed to patient insurance at some visits but not others. TASCS will allow users to indicate how the service should be billed at each visit – or whether it will be provided outside of Fairview or UMP.

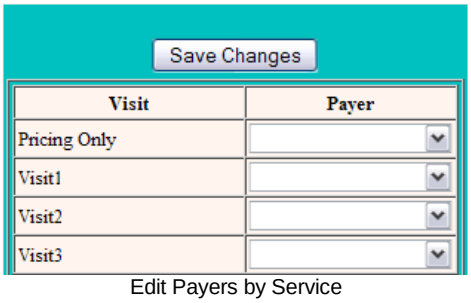
If you don't see a visit displayed, return to the Visits screen and make sure you checked the box indicating that medical or lab services are needed at the visit. This box must be checked in order for the visit to appear on the Payer screen.

The visits and services appear as hyperlinks. You may choose to populate the payer information by visit or by service. If by visit, then click on the desired visit link. If by service, click on the desired service link. Either way, a pop-up window appears in order for you to select a payer. The payer drop-down options are listed below:

- Research Account
- Patient/Insurance
- Other



Edit Payers by Visit



Edit Payers by Service

Click on the "Save Changes" button when you complete a pop-up screen. TASCS will display the payer information you've chosen on the Payers screen as text. You may

reselect a visit or service link if an error was made and you will re-enter the pop-up screen. Continue to use the links (either by service or visit) to populate the Payer screen.

R - Research Account
Ins. - Pt/Insurance
O - Other

When all services required by the protocol have payers selected, click on the "Submit to Providers" button. Service Providers will receive an automatic e-mail (with a copy to the protocol and Billing Contacts) informing them that there is a protocol to review. Researchers will receive a prompt to attach their protocol to an e-mail to send to Fairview and UMP.

If you prematurely select "Submit to Providers" you should contact Fairview (612-672-6737 or 612-672-7678) to let them know your request is not yet complete.

Service Provider Responsibilities

Providers will review the submitted protocol and billing plan that is now available as a TASCS report (Billing Grid). If the billing plan indicates that the patient/insurance will be billed for study related services, then further review is required to determine if the study is a qualifying clinical trial under the National Coverage Decision (Medicare's Clinical Trial Policy). Fairview will alert Investigators, early in review, if concerns are identified with the billing plan or if the study is not a qualifying clinical trial.

When the coverage analysis is completed, Providers will click the "Coverage Analysis Complete" button on the Protocol screen. This will initiate a TASCS generated e-mail to the Protocol Contact and the Billing Contact to inform them that the billing grid is now ready.

Researcher Responsibilities

After receiving email notification that the billing grid is available, go to the Report menu and select Billing Grid Report. Print the billing grid and have the PI review, sign, and date.

Submit the signed/dated billing grid with the IRB application.

Step 5 – Research Pricing

For each service with "Research" listed as the payer, a price must be entered into TASCS by the Provider.

Provider Pricing screens are only available to Fairview's Research Administration and UMPhysicians Patient Financial Services employees.

Service Provider Responsibilities

Pricing Complete

Status	Write-in Service Description	Service Location	Fee schedule	Discrepancy
Inactive	Investigational Drug Services: Study Set-Up	Fairview Hospital	Adult CV Global	
Inactive	Investigational Drug Services: Dispense investigational drug	Fairview Hospital	Adult CV Global	
Inactive	Investigational Drug Services: Dispense commercial drug	Fairview Hospital	Adult CV Global	
Inactive	Investigational Drug Services: REGISTER ONLY	Fairview Hospital	Adult CV Global	
Active	MRI with contrast	Fairview Hospital	Adult CV Global	
Active	EKG (lab)	Fairview Hospital	Adult CV Global	
Active	MRI with contrast	UMP Imaging Center	Adult CV Global	
Notes:				

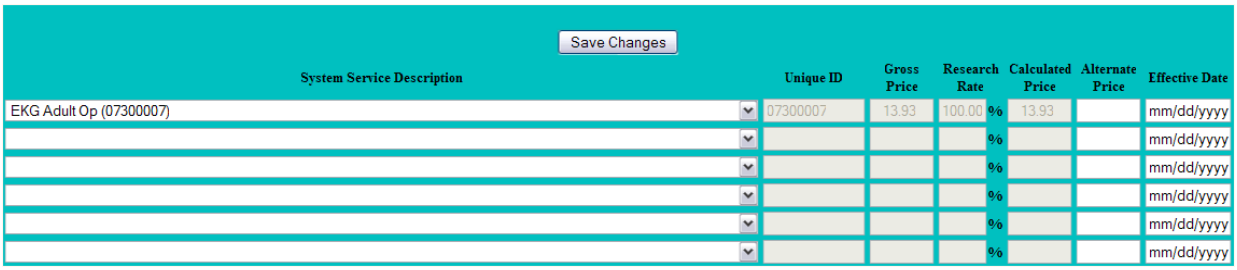
Save Notes

Select the appropriate fee schedule from the drop down for each service listed based on the service location. Click on the Write-In service description to advance to the pricing screen.

Save Changes

System Service Description	Unique ID	Gross Price	Research Rate	Calculated Price	Alternate Price	Effective Date
			%			mm/dd/yyyy
			%			mm/dd/yyyy
			%			mm/dd/yyyy
			%			mm/dd/yyyy
			%			mm/dd/yyyy

The Write-In service description and desired service location are provided as header information on the pricing screen. Use the drop-down menu in the Service Description column to locate the requested service. The remainder of the row will auto-populate. If additional services are typically needed (e.g., Colorflow Doppler when "Echo" is requested, or contrast material for Nuclear Medicine tests), add the service on the next line. Click the "Save" button to return to the previous screen.



Continue to price each service requested. When finished choose the "Completed" button. This action generates an email notice to the Protocol and Billing Contacts that prices are available.

Researcher Responsibilities

To prepare the protocol budget, go to the Report menu and select Research Prices Report. This report will list the prices for services to be provided by Fairview/UMP and billed to the research account. The pricing information is based on the data entered on the Services and Payers screens.

Complete the Proposal Routing Form (PRF) process as usual and include the TASCS number where requested on the PRF. The TASCS number is auto-generated by the system and found at the top of each TASCS screen.

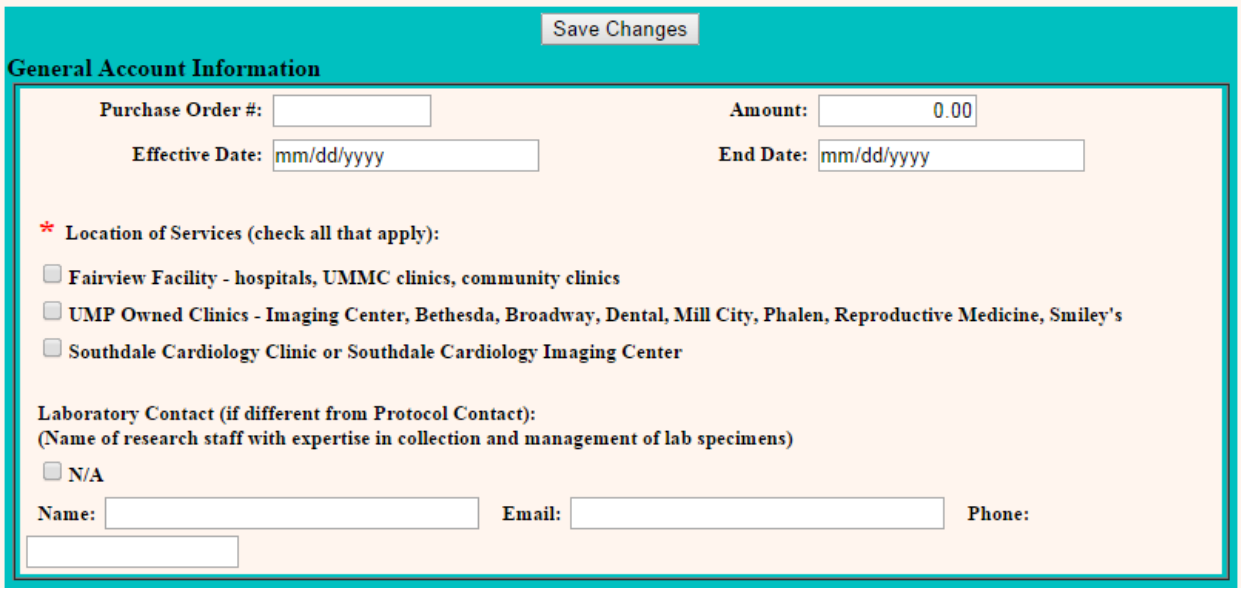
When the account number (EFS chart string) is assigned, request/prepare a purchase order for the research services that will be paid for by the research account.

When a purchase order number is available, it is time to complete the Account/Lab Set-Up Screen. Go to the "Edit" menu and choose "Account/Lab Set-Up." Then search by TASCS number (or any search term of your choosing) to locate the protocol.

Step 6 - Account and Lab Set-Up Entry Screen

Required Information for Step 6

Purchase Order #
Amount
Effective Date
End Date
Location of Services


Save Changes
General Account Information
Purchase Order #:
Amount:
0.00
Effective Date:
mm/dd/yyyy
End Date:
mm/dd/yyyy
* Location of Services (check all that apply):
Fairview Facility - hospitals, UMMC clinics, community clinics
UMP Owned Clinics - Imaging Center, Bethesda, Broadway, Dental, Mill City, Phalen, Reproductive Medicine, Smiley's
Southdale Cardiology Clinic or Southdale Cardiology Imaging Center
Laboratory Contact (if different from Protocol Contact):
(Name of research staff with expertise in collection and management of lab specimens)
N/A
Name:
Email:
Phone:

General Account Information

Enter information into the required fields in the General Account Information section of the screen. You must complete the information in this section before clicking on the "Save Changes" button at the top of the screen. When you click on the "Save Changes" button, the Providers will receive an email alerting them to establish your research billing accounts.

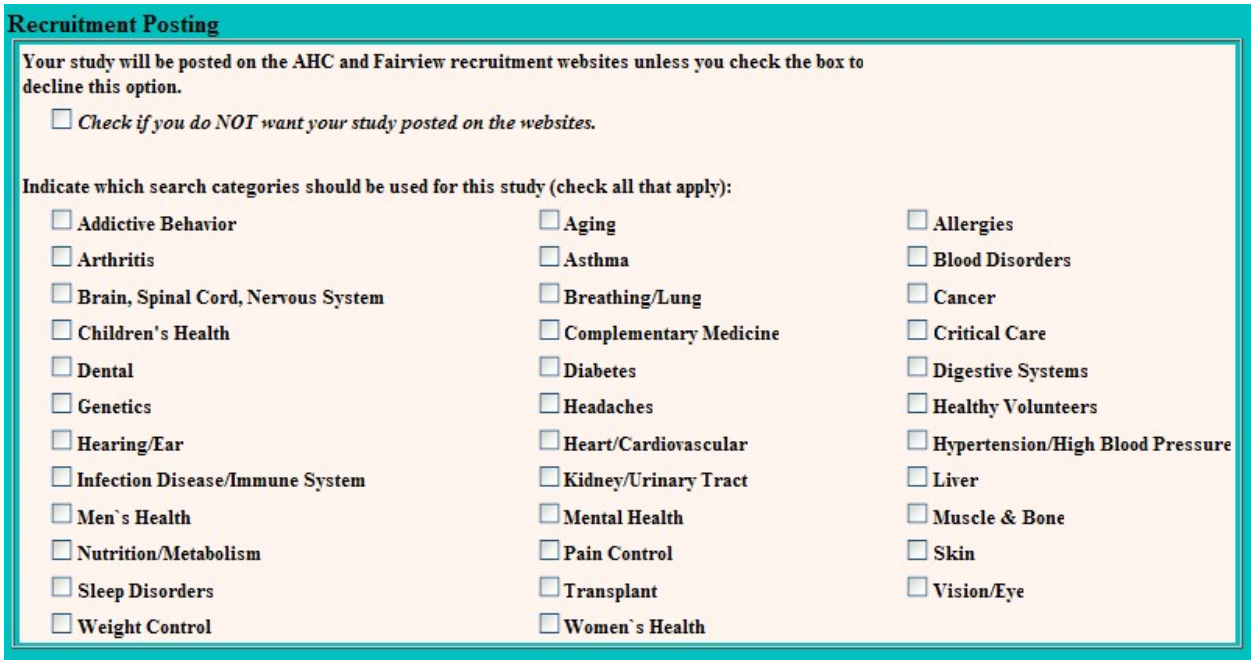
After selecting "Save Changes", a new General Account Information section will appear on the Account/Lab Set-Up Screen. This will allow for additional purchase orders to be added.

The remaining sections of this screen do not need to be populated in order to "Save Changes".

Lab Information
Laboratory site needed (check all that apply):
UMMC East Bank (University)
UMMC West Bank (Riverside/Amplatz)
Fairview Southdale Hospital
Fairview Ridges Hospital
Fairview Lakes Hospital
Fairview Northland Hospital
Fairview Range Hospital
UMP Owned Clinic - Imaging Center, Bethesda, Broadway, Dental, Mill City, Phalen, Reproductive Medicine, Smiley's
Fairview Clinics - includes Maple Grove Ambulatory Care Center
Using Fairview Labs to analyze specimens?
(Check Yes, No or both below. If both, complete the In House and Outside Lab sections.)
Yes, complete the "In House Lab Analysis" section below
No, complete the "Outside Laboratory" section (for collection, processing or packaging/shipping only)

Lab Information

The lab portion of the Account/Lab Set-Up screen is required if you are using services from a Fairview lab. The “In-House” section must be completed if you want your lab specimens analyzed in a Fairview lab. The “Outside Lab” section is completed when you want Fairview lab to collect or process samples, but will send the samples to a non-Fairview lab for analysis. Any questions about how to complete the fields on this screen should be directed to Fairview at (612) 672-7690.



Recruitment Posting

TASCS will send a notice to the Fairview's recruitment website to post your study for recruitment. If you do not want your study posted for recruitment, check the box to decline.

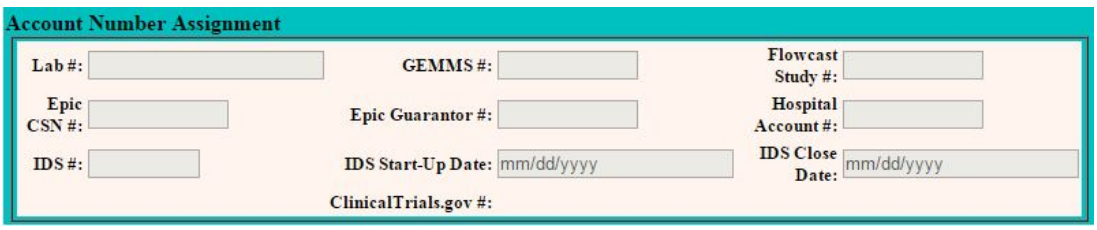
Check one or more health categories by which the public should search for your study.

Click on "Save Changes" when you have completed this screen.

Provider Responsibilities

As indicated above, an email will be automatically generated to Service Providers (with a copy to the Protocol Contact and Billing Contact) for review and set up of account numbers.

Fairview Research Administration, UMPhysicians Patient Financial Services and Fairview Laboratories will review the Account and Lab Set-Up screen. UMPhysicians will assign a Flowcast case number to the study and enter it into TASCS. Fairview will assign EPIC number and laboratory account numbers (U#s or B#s) and enter them into TASCS. Providers will communicate with the appropriate contact (either Protocol or Billing) if more information is needed.



Providers populate the “Provider Accounts” section on the bottom of the Account and Lab Set-Up screen and choose the “Account Set-Up Complete” button.

The Protocol and Billing Contacts will receive an email stating the account numbers have been assigned. The account numbers will display on the Protocol screen and on the Account and Lab Set-Up screen.

Fairview Lab will continue to create the laboratory requisitions (lab slips) and send to the requesters.

After Subject Enrollment

This section includes data entry and communication processes from the point of subject enrollment through study closure. The following TASCS screens are described in this section:

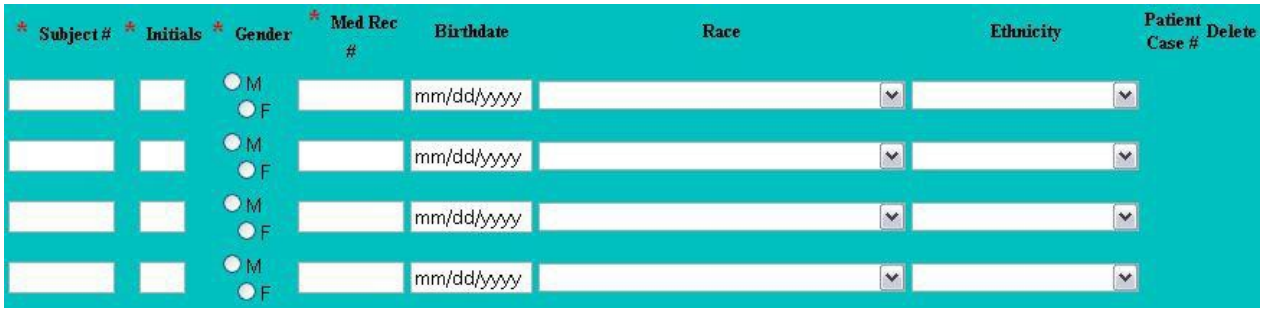
- Subjects
- Subject Tracking Form
- Service Discrepancy.

Step 7 - Subject Entry Screen

Go to the "Edit" menu and choose "Subjects." Then search by TASCS number (or any search term of your choosing) to locate the protocol.

Required Information for Step 7

Subject #
Initials
Gender
Med Rec #
Birthdate



Researcher Responsibilities

Subject #

Create a subject number that is meaningful to you and enter into this field. Many users choose to use the subject number assigned by the study sponsor. You may change a subject number if needed (i.e., change from screening number to randomization number).

Initials

Enter the subject's initials.

Gender

Indicate the subject's gender by clicking on the "M" or "F" button.

Medical Rec #

Enter the subject's Fairview medical record number. If the subject is not a Fairview patient, use the Placeholder Medical Record number described below.

Placeholder Medical Record Number

This information applies to research where individual subjects will not use Fairview or UMP services. If a subject doesn't have a Fairview medical record number, enter ten "3s" (3333333333) as the medical record number placeholder.

Use the placeholder medical record numbers with caution. Inappropriate use of placeholder medical record numbers places researchers and service providers at risk. For questions contact the TASCS Support.

You are required to enter information into TASCS within 72 hours of a subject signing a consent form.

For studies utilizing Fairview services: As of September 1st, 2014 it is the researcher's responsibility to enroll and withdraw patients from studies in EPIC directly. Please contact Fairview Research Administration (research@fairview.org) with questions regarding this process.

Provider Responsibilities

When the consent date is entered and saved on the Subject Tracking Form, an auto-email is sent to the Providers. UMP will create a patient case number for all subjects enrolled in studies using UMP services.

UMP will enter case numbers for all subjects entered into the TASCS system on or after August 18, 2008.

In studies where consent to participate in the study occurs months in advance of any further screening for eligibility, the date of consent must still be entered within 72 hours after consent is signed. Subjects found to be ineligible will have to be withdrawn from the study when it is known they are ineligible.

Using the Encounter Form

With the implementation of EPIC, most service areas have converted to electronic charge routing and no longer use paper forms/tickets. There are still some service areas at Fairview and at University of Minnesota Physicians that continue to use paper forms/tickets – including the research Encounter Forms. Please see Appendix G for details.

When enrollment for the protocol can begin and a potential subject is identified – follow these steps:

1) Go to the Reports menu.
2) Print visit specific encounter form(s) from TASCS. The visit specific forms will include only those services to be provided by Fairview or UMP and to be billed to the research account.

Encounter forms and lab slips, when required, signal Providers to bill services to the research account.

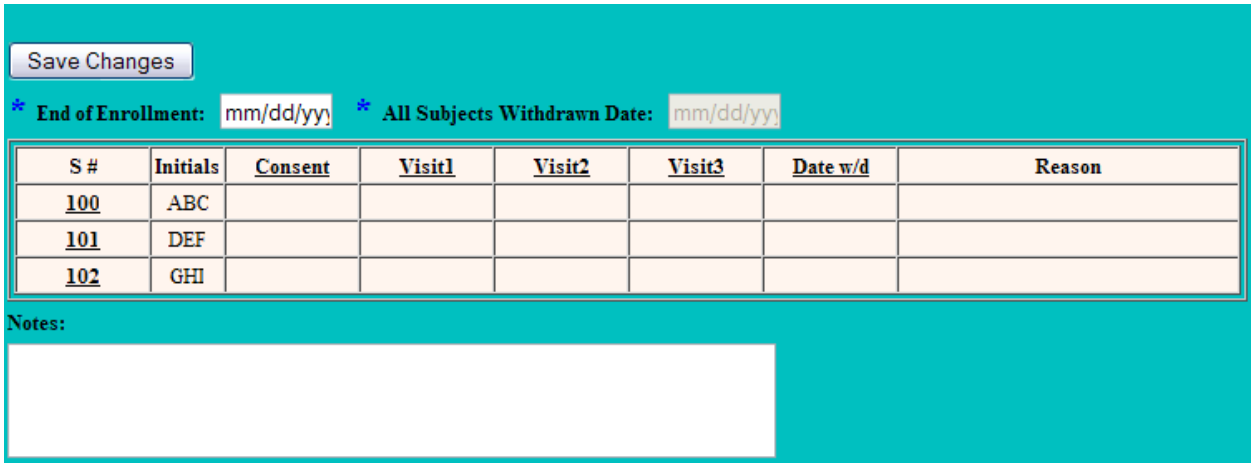
One-time or “invoiceable” items should be written in the box at the bottom of the encounter form and indicated, on the Subject Tracking Form Entry screen, as an additional service not pre-printed on the encounter form.

Encounter forms, when required, can be printed specific to subjects and visits. It is also possible to print a visit specific encounter form that does not include information about any specific subject. If researchers use these generic forms, information about the subject must be handwritten on the encounter form.

Visit and subject specific encounter forms will only be available in TASCS if the Services and Payers screens have been completed.

Step 8 - Subject Tracking Form Entry Screen

Dates must be entered when a subject is consented, a visit is completed, and when a subject is withdrawn. Each of these dates must be entered within 72 hours of the event.



Entering Visit Dates

The Subject Tracking Form displays the visits you defined and the subjects you have enrolled as a table. Both the Subject #s and the Visit dates are provided as hyperlinks. You may enter visit dates by choosing either the individual subject # link or the visit link. Selecting a link will open a pop-up window.

The pop-up window includes a column titled “Additional Services?” You must answer the question below by selecting “yes” or “no” from the drop-down menu:

Were additional services used at the visit (e.g., not planned for this visit and they were not pre-printed on the Encounter Form or Research Lab Slip)? If there were additional services, indicate by choosing "Yes." If there were no additional services, indicate by choosing "No."

One-time or “invoiceable” items should be written in the box on the encounter form and indicated, by answering the question “Y” on the Subject Tracking Form screen for the visit, as an additional service not pre-printed on the encounter form.

Once you have answered the above question by choosing “Yes” or “No,” you enter the visit date. When finished, click the “Save Changes” button to exit the pop-up screen. The Subject Tracking Form is refreshed and displays the data you entered as text. If you need to edit the data, click on either the Subject # or Visit link and repeat the above process.

Whenever the answer to the question is “yes,” the Providers will receive an email notification and the Researcher will be prompted to complete another TASCS screen called “Service Discrepancies” screen. This screen looks similar to the original Services screen.

End of Enrollment

Enter a date in this field when no further subjects will be recruited for participation. Entry of a date in this field will send a notice to the recruitment website to discontinue your posting. This field must be populated before you can enter information into the “All Subjects Withdrawn Date” field.

All Subjects Withdrawn Date

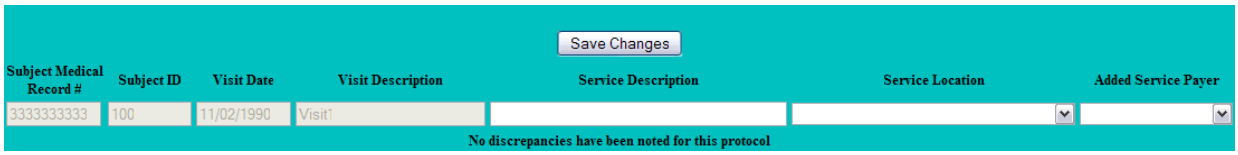
Enter a date in this field when all subjects have either completed the protocol or withdrawn from the study. Once a date is entered into this field, the following occur:

- No further data may be entered on the Subject Tracking Form screen
- No encounter forms will be available for the study
- Providers will receive an email stating that all subjects have been withdrawn and no further charges will be generated
- Providers will remove the research indicator from the subject’s billing account(s)

Service Discrepancy Entry Screen

Required Information

Service Description
Service Location
Added Service Payer



TASCS will auto-populate the Subject Medical Record #, Visit Date and Visit Description fields based on stored data. You must complete the remaining three fields: Service Description, Service Location and Added Service Payer.

Researcher Responsibilities

Service Description

Enter the name of each test or procedure using the clearest and most specific terms possible to indicate the service that was added at the visit.

Service Location

Indicate where the service was provided. The Service Location drop down menu includes the same options displayed on the Services screen:

- UMMC Clinic
- UMP Clinic
- Fairview Clinic (Includes Maple Grove)
- Fairview Hospital
- UMP Imaging Center
- Other

Added Service Payer

Indicate who will pay for the added test/procedure at this visit. The drop-down options for this field are:

- Research Account
- Patient/Insurance
- Other

Service Provider Responsibilities

Review the discrepancy and ensure the charges are directed according to the instruction provided on the Service Discrepancy screen.

Add research modifiers to the charge if the service is research related and billed to Medicare.

Update/maintenance Requirements

Complete information is required in TASCS in order to comply with the policy. Updates are required as information becomes available. The following data fields are marked with blue asterisks indicating they are required. Please refer to Appendix E for field definitions by screen. The fields are listed by the screen on which they appear.

Protocol Entry

EFS Fund
Project
Program
Start Date
End Date
(CPRC) Number
(IRB) Number
(IRB) Approval Letter Date
Investigational Device Exemption (IDE) #
Humanitarian Device Exemption (HDE) #

Subject Tracking Form

End of Enrollment
All Subjects Withdrawn Date

Routine compliance monitoring will identify fields marked with either red or blue asterisks that are missing data or have incomplete data as these are required.

Section III - How-To

Protocols without Services

A checkbox has been added to the Protocol screen in the middle of the "General" section. The checkbox is designed to add clarity for information added to TASCS that does not involve Fairview or UMP services. Examples of TASCS use that may fall into this category include (but are not limited to):

- The research is conducted at another clinical site (VA, HCMC, etc.)
- The research is a registry study or medical record review
- The research staff is using TASCS for internal purposes only (e.g., time card tracking)

The checkbox reads as follows:
No services needed from Fairview or UMP on this protocol.

- Services refer to tests, procedures, clinic space, clinic visits, physician time, lab services, pharmacy services or hospital services that are required to carry out the protocol.

When the box is checked, Fairview will not review the protocol for coverage analysis. It is also assumed that no pricing information or billing accounts are needed. In addition, there are no emails generated by TASCS to alert Fairview or UMP regarding the subsequent entries in TASCS. Therefore, if subjects are entered into TASCS, no alert is sent to Fairview or UMP and the subjects will not be flagged as research participants in any of Fairview's or UMP's systems.

Checking the box excludes the protocol from some of the routine exception reporting functions in TASCS.

If the research changes and services are needed, the user would uncheck the box and all the usual functions in TASCS will be restored.

IDS Register Only

This information applies to those studies that plan on managing the investigational drug/agent independently without the assistance of Investigational Drug Services.

1. Go to the **New** menu and choose **Protocol**.
2. Complete the required fields on the Protocol screen and **Save Changes**.
3. Click on the **Visits** link to advance to the next screen or go to the **Edit** menu and choose **Visits**. Click the checkbox next to the **Start Up** visit indicating that Medical/Lab Services will be used at this visit. Uncheck the boxes for the remaining pre-populated visits. Click on the **Save Changes/Select Services** button.
4. On the Services screen, change the status on all the IDS services to **Inactive** except for the "IDS: Register Only" service. Make sure "IDS: Register Only" is indicated as **Active**.

5. Click on the **Save Changes/Choose Payers** button to advance to the Payers screen.
6. On the Payers screen, choose **Research** as the payer in the Start-Up visit column next to IDS Register Only (even though no charges will be generated by Fairview).
7. Click on **Save Changes** and then **Submit to Providers**.
8. Attach the protocol via the automatic TASCS email.
9. Complete the IDS Register Only form (available at www.fairview.org/research) under Forms.
10. Send completed form via email to IDS: IDSPharmacy@fairview.org.

If requesting prices from Investigational Drug Services (IDS), you need to provide sufficient information for IDS to evaluate and price the requested services. Information may be added in the comment box on the Services screen in TASCS or attached in lieu of a protocol.

Pricing Only

You can request research prices from Fairview and UMP in order to help determine study feasibility for grant submissions when no protocol has been developed. There may be additional charges associated with these services that are unknown prior to the availability of a full protocol for the study.

To request prices for services, follow these steps:

1. Go to the **New** menu and choose **Protocol**.
2. Complete the required fields on the Protocol screen and **Save Changes**.
3. Click on the **Visits** link to advance to the next screen or go to **Edit** menu and choose **Visits**.
4. Ensure that the "Pricing Only" visit is checked, indicating that Medical/Lab Services are needed. Click on the **Save Changes/Select Services** button to advance to the next screen.
5. Change the status of unused services to **Inactive**. Enter services that need pricing and **Save Changes**. Click on the **Save Changes/Choose Payers** button when all services have been entered.
6. Populate the Payers screen using "Research" as the payer. Click on the **Save Changes** button and then **Submit to Providers**.
7. Disregard the instructions on the notice directing you to attach your protocol to the auto-email. Feel free to include a proposal or other documents that will help clarify the services you have requested.

Should your study be funded, you will need to update the Protocol, Visits, Services and Payers screens to accurately reflect your protocol. Prices will be sent based on the updated information.

Subcontracts, Professional Services Agreements (PSA) and Contracts for Professional Services (CPS)

Information in this section applies to studies where a prime award or contract has been granted to one institution and an additional contract (agreement) is needed in order to purchase supplies or labor from a separate organization. This process is most commonly used when the University is the prime award recipient and a subcontract, PSA or CPS is needed between the University and Fairview.

1. Go to the **New** menu and choose **Protocol**.
2. Complete the required fields and check the box at bottom of the first section (General) that says "Check here if you need a new subcontract with Fairview or UMP."
3. Click on **Save Changes** to save the screen.
4. Fairview or UMP will notify the Protocol Contact that the request was received and request a work-scope and budget.
5. Fairview or UMP will create the Statement of Intent (or other necessary documentation), obtain Fairview signatures and return to signed document to the Protocol Contact.
6. No further documentation is required in TASCS.

Humanitarian Device Exemptions (HDEs) and Humanitarian Use Devices (HUDs)

1. Go to the **New** menu and choose **Protocol**.
2. Complete the required fields on the Protocol screen.
3. In the IRB section of the Protocol screen, indicate the HDE number, and save the screen.
4. Click on the **Visits** link to advance to the next screen or go to the **Edit** menu and choose **Visits**.
5. On the "Visits" screen, add a single visit called "HUD Surgery." and uncheck the boxes for the remaining pre-populated visits. Click the **Save Changes** button, NOT the "Save Changes/Select Services" button.
6. Fairview will contact you for additional information needed to submit the HUD use to Medicare.
7. Once HUD use begins, enter patient information on the Subjects screen and complete the Subject Tracking Form screen by adding the consent and surgery dates within 72 hours of each event.

Bulk Specimen Processing Services

This applies to the following:

- ❖ laboratory samples that come from other sites for processing in a Fairview lab

- internal archived/stored laboratory specimens (including pathology) that are pulled for new testing and are analyzed with no patient identifiers

1. Go to the **New** menu and choose **Protocol**.
2. Complete the required fields on the Protocol screen and **Save Changes**.
3. Click the **Visits** link to advance to the next screen or go to the **Edit** menu and choose **Visits**.
4. Add a single visit called “Specimens” and uncheck the boxes for the remaining pre-populated visits. Click the **Save Changes/Select Services** button.
5. On the Services screen, add lab services with “Fairview Hospital” as the Service Location. Click on the **Save Changes/Select Payers** button.
6. Choose **Research** as the payer for the services. When finished, click on the “Submit to Providers” button.
7. When you receive the pop-up that says submit the protocol attach any available lab instructions in place of the protocol.
8. When funded, obtain a purchase order from your departmental accountant and complete the Account/Lab Set-Up screen.
9. Fairview will populate the billing account numbers in TASCS and the lab will send a study specific lab requisition to be used when samples are sent to the lab.
10. No further documentation is required in TASCS.

Making Changes to Required Fields (by entry screen)

Protocol Screen

Field Name: Status
The status field indicates whether the study is active or inactive. You can further clarify the active status with “Approved”, “Future Protocol”, or “In the Approval Process”. Changing from one active status to another can be done by all users.

Changing the status from Active to Inactive will require the following conditions:
1. All subjects are withdrawn in TASCS.
2. All Subjects Withdrawn date is entered (entering an All Subjects Withdrawn date also requires the entry of an End of Enrollment date).

After changing the protocol status to Inactive (and saving the change), the status becomes grayed out and locks the protocol from any further changes. Additional changes to the protocol will require TASCS Support assistance. Please contact TASCS Support (tascs@umn.edu) to discuss options.

The Inactive-Duplicate status indicates that the protocol is a duplicate of an existing protocol in TASCS. Inactivate the duplicate protocol by changing the status to Inactive-Duplicate and then saving changes.

Choosing the Inactive-Duplicate status and saving changes will remove the protocol from the list of viewable protocols. For any questions about the Inactive-Duplicate status please contact TASCS Support (tascs@umn.edu) for help.

Field Names: PI, Billing Contact, Protocol Contact, Sponsor, Short Protocol Title, and Full Protocol Title
Entries in these fields can be changed at any time on protocols with an Active status.

Field Name: Dept ID
The Dept ID drives security in TASCS and limits access to those associated to a specified Dept ID. Once a Dept ID has been selected and saved, the number cannot be changed without the assistance of TASCS Support. Please contact TASCS Support (tascs@umn.edu) for help.

Field name: IRB #
The IRB # is an identifier for the study in the IRB's database. Once entered into TASCS, the number cannot be changed without the assistance of TASCS Support. Please contact TASCS Support (tascs@umn.edu) for help.

Field Name: IRB Approval Letter Date
The IRB Approval Letter Date is the date of the IRB approval letter. Once entered, this date cannot be changed without the assistance of TASCS Support. Please contact TASCS Support (tascs@umn.edu) for help.

Visits Screen

Field Name: Visit description
The visit description indicates the data collection time point for the study. Once entered and saved, the description cannot be changed except by deleting it and entering a new one. To do so, check the delete box for the incorrect visit description and save changes. Deleting a visit should only be considered during the initial setup of the study. Deleting a visit after other data are associated with that visit could be very time consuming.

*When a Delete box is grayed out it indicates that Payers and/or Tracking data are associated to that visit. The associated data will have to be removed from TASCS before deleting the visit. Please contact TASCS Support (tascs@umn.edu) to discuss options.

Services Screen

Field Names: Status, Medical/Lab Services, Service Location
You can change the Status, Medical/Lab Services, or Service Location before submitting to providers.

Service description and service location are locked permanently after submitting to providers.

Please use the steps below to change service description and/or service location after submitting to the providers:

1. Click on Unlock and Modify and then click OK on the pop-up prompt.
2. Change the status of the incorrect service to Inactive and save changes.
3. On a blank service line, enter the correct service description, select the correct service location, and save changes.

4. Repeat step 2 until all corrections are completed and click on Save Changes/Choose Payers.
5. For each new corrected service, select the payer for the service for all visits requiring the service.
6. Repeat step 5 until payers for all services have been selected and click on Resubmit to Providers.

Payers Screen

How to: change payer after submitting to providers
Payer data indicates who pays for a service at a particular visit. You can change payer data before submitting to providers.

After submitting to provider, the screen is locked to prevent further modification. Please use the steps below to change payers after submitting to the providers:

1. Click on Unlock and Modify and then click OK on the prompt.
2. Click on a visit link to change payers for services happening at that visit, or
3. Click on a service link to change payers for the service at study visits.
4. Repeat step 2 or 3 until all payers have been selected and click on Resubmit to Providers.

Subjects Screen

Field Name: Subject #
For Active status protocols, the subject number can be changed at any time after the initial entry. A subject number for each subject must be unique within the subjects enrolled in a protocol.

Field name: Initials
For Active status protocols, subject initials can be changed at any time after initial entry.

Field Name: Gender
For Active status protocols, the subject's gender can be changed at any time after initial entry.

Field Name: Med Rec #
The Fairview medical record number is a 10 digit number, starting with 00, and can be changed, for Active status protocols, at any time after initial entry.

Field Name: Birthdate
For Active status protocols, the subject's date of birth can be changed at any time after initial entry.

Subject Tracking Screen

How to: Update a subject visit after a withdrawn date has been entered
Because a subject should not complete a visit after they have been withdrawn, TASCS prevents entry of a visit date after a subject has been withdrawn.

Please use the steps below to update visit tracking for a withdrawn subject:

1. Click on the subject # that needs to be updated.
2. For Date w/d, change the Additional Service from Yes or No to "blank", if applicable, and delete the date.
3. For a visit that needs updating, select Yes or No for additional service accordingly and enter the visit date.
4. Repeat step 3 until all visits for the subject are updated
5. Update the Date w/d visit (including Additional Services, if any), select the Reason, and save changes.

Service Discrepancies Screen

Field Name: Service Description
For Active status protocols, the description of the additional service can be changed at any time after the initial entry.

Field Name: Service Location
For Active status protocols, the location of the additional service can be changed at any time after the initial entry.

Field Name: Payer
For Active status protocols, the payer of the additional service can be changed at any time after the initial entry.

How to: Delete a service discrepancy

If, by mistake, a discrepancy was indicated by selecting Yes for additional service on the Subject Tracking Screen, and no discrepancy was entered, then change the Yes to No and save changes.

Appendices

Appendix A -Contacts

TASCS Support

Address:	TASCS Support Mail Code 1932 717 Delaware St. SE Minneapolis, MN 55455
Email:	tascs@umn.edu
Fax:	612.625.2695
Phone:	612.626.5203

Fairview Research Administration

Email:	research@fairview.org
Contacts:	http://www.fairview.org/Research/S_034225

University of Minnesota Physicians

Email: pfs-research@umphysicians.umn.edu

Specific provider contacts are also available in TASCS via the Links menu.

Forms

TASCS Access

TASCS Access Request Form

Name: _____ **Title:** _____

Address 1: _____ **Phone:** _____

Address 2: _____ **Email:** _____

City: _____ **State:** *MN* **Zip Code:** _____

Request Type: *New Access*

Access Type: *Standard*

Access Type Descriptions:

CTO - *for Masonic Cancer Center Clinical Trial Office employee*
CTSI - *for Clinical Translational Science Institute employee*
Encounter Form Only - *provides access to Encounter Form only*
IRB - *for Institutional Review Board employee*
Provider - *for Fairview or UMP administrative employee*
Report Only - *provides access to reports only (no training required)*
RIOP - *for Research Integrity and Oversight Programs employee*
SPA - *for Sponsor Project Administration employee*
Standard - *for standard access by Dept ID*

Researcher Role(s): *Check all that apply*

- ☐ Principal Investigator
- ☐ Protocol Contact / Clinical Research Coordinator
- ☐ Billing Contact / Administrator

Dept ID:
To determine DEPT ID numbers, contact the administrator or accountant in your home department.

By signing, I agree that I have read and understand the University of Minnesota's Acceptable Use of Technology Resources document, and have completed University HIPAA training. I agree to use TASCS only for work-related business and not to share my password with anyone. I agree to only share the information obtained from TASCS with personnel who have a legitimate work-related need for the information.

Applicant Signature: _____ **Date:** _____

Remember to attach the e-mails stating that HIPAA training courses were successfully completed or attach copy of training record

Supervisor Name: _____

Email: _____ **Phone:** _____

Supervisor Signature: _____ **Date:** _____

No "supervisor" signature required for Principal Investigator

For internal use: Date Rec'd _____ *Date Access Given* _____ *Initials* _____

TASCS Support 612.626.4612 tascs@umn.edu Fax: 612.625.2695

Add/Remove Personnel or Sponsor

Add/Remove Personnel or Sponsor

Personnel **Complete this section if you want to add or remove a Principal Investigator, Protocol Contact or Billing Contact to the drop-downs.*

Add
- ☐ Principal Investigator
- ☐ Protocol Contact
- ☐ Billing Contact

Remove
- ☐ Principal Investigator
- ☐ Protocol Contact
- ☐ Billing Contact

Title: _____

First: _____ MI: _____ Last: _____

Phone: _____ Fax: _____ email: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Sponsor **Complete this section if you want to add or remove a sponsor to the drop-down.* ☐ Add ☐ Remove

Sponsor Name: _____

Funding Type: _____

Funding Type Description:

Business/Industry: Research sponsored AND funded by a for-profit company or entity. **If an investigator develops a protocol and obtains funding from a business, the research is sponsored by the investigator, not the business and it would not fall into this category.** Common examples in this category include research sponsored by pharmaceutical and device companies to investigate products in line with FDA regulations.

Federal: Research sponsored OR funded by a federal entity. This category includes protocols with a blend of federal money and other sources (private, commercial, etc.). It also includes research funding passed through other organizations if the original (prime) funding source specific to the research is a federal entity. Common examples in this category are cooperative group studies and NIH multi-center trials.

State: Research sponsored OR funded by a MN state organization or entity. An example of state funding is research paid for by the Tobacco Settlement. Research sponsored or funded by states other than MN should be included in the "Other" category (see below).

University funds: Research sponsored AND funded by aUniversityofMNschool, department or organization. Examples in this category include seed money from a department or grants awarded from University funds. An investigator-initiated protocol conducted using internal funds would fall into this category. If the research is conducted by University staff or faculty using external funds, then it falls into one of the other categories.

Other: Research sponsored OR funded by an organization, individual or entity not described in the above four categories. **Investigator-initiated studies fall in this category**. If a non-profit organization received federal money to support a specific research project, then the research is consider "Federal" rather than "Other" even though the non-profit may be the sponsor (see comment above in Federal section regarding "pass throughs").

TASCS Support 612.626.4612 tascs@umn.edu Fax: 612.625.2695

Appendix B -Service Locations

UMMC Clinics

1A Neuro, Neuro Surg, PMR, EEG/EMG
2A Transplant Center
3A Primary Care
4A Pediatrics
5A Allergy, Asthma, Derm, PFT Lab
5A Sleep Disorder
6A Medicine
8A ENT
9A Eye
3B Cardiovascular Center
5B BMT
6B Delaware St
1C Women's Health Center
1E Surgery, Colon-Rectal, GE, Weight Mgmt
1E Peds Urology
Derm Surg and Laser
Masonic Cancer Center
Masonic Breast Center
Masonic Day Hospital
Mayo B435 Prostate Cancer and Urology
Riverside Ortho
Riverside University Specialists
Riverside Urology
Riverside West Psychiatry

UMP Clinics

Family Medicine
Center for Sexual Health
Smiley's Clinic
Phalen Village
Broadway Family Medicine
Bethesda Clinic
Riverside Endoscopy Center
Imaging Center
Reproductive Medicine Center

Fairview Clinics

Maple Grove Medical Center
Columbia Park Medical Group
Fairview Cedar Ridge
Fairview Oxboro
Fairview Ridges
Fairview Eagan
Fairview EdenCenter
Fairview Crosstown
Fairview Elk River
Fairview Lino Lakes
Fairview Bass Lake
Fairview Children's
Fairview Hiawatha
Fairview Northeast
Fairview Uptown

Fairview Hospitals

University of MN Medical Center, Fairview
Fairview Southdale Hospital
Fairview Ridges Hospital
Fairview Lakes Medical Center
Fairview Northland Medical Center
Fairview Red Wing Medical

UMP Imaging Center

On the UMMC Campus.

Other

Not one of the locations described above.

Appendix C -Automatic Emails

TASCS employs automatic emails as a notification tool. The chart below lists emails and to whom they are sent.

Emails	Principal Investigator	Billing Contact	Protocol Contact	Fairview	UMPhysicians	Lab	IRB
Account Setup		x	x				
Additional PO Entered		x	x	x			
All Subjects Withdrawn		x	x	x	x		
All Subjects Withdrawn Correction		x	x	x	x		
Billing Accounts		x	x	x	x	x	
Billing Contact Change		x	x	x	x		
Budget Info Change	x	x	x	x			
Coverage Analysis Complete	x	x	x		x		
IDE/HDE Alert		x	x	x			
Modification Detail	x	x	x	x			x
Patient Case Number		x	x				
PI Contact Change	x	x	x	x			
Pricing		x	x				
Protocol Contact Change		x	x	x			

Emails	Principal Investigator	Billing Contact	Protocol Contact	Fairview	UMPhysicians	Lab	IRB
Protocol Status Change		x	x	x	x		
Protocol Status Correction		x	x	x	x		
Services Alert		x	x	x			
Service Discrepancy Alert		x	x	x	x		
Service Discrepancy Alert Correction		x	x	x	x		
Services/Payers Modification		x	x	x			
Short Title Change		x	x	x	x		
Sponsor Change		x	x	x			
Subcontract Alert		x	x	x			
Subject Consented		x	x	x	x		
Subject Consented Date Change		x	x	x	x		
Subject MRN Change			x	x	x		
Subject Withdrawn		x	x	x	x		
Subject Withdrawn Date Change		x	x	x	x		

Each email is sent based on a predefined trigger. When a certain action is taken, it will trigger the auto email, which is sent to the contacts listed in the above chart.

Each email will provide the TASCS ID number, the PI's name and the short study title as the first line of text. The last text line will indicate the user who triggered the email. The details of each email and the trigger are described below:

Account Setup

Trigger: when Providers click on the Account Setup Complete button.
Email Subject: Account Setup [TASCS ID]
Email Message: Your research billing accounts have been set up by the Providers and the account numbers are available in TASCS on the Protocol screen.

Encounter forms are now available for your use and are found in the Report menu in TASCS. If you requested Lab services, the Fairview Lab will create a study-specific requisition slip and send to you directly.

All Subjects Withdrawn

Trigger: when a date is entered into the All Subjects Withdrawn Date field and saved.
Email Subject: Subject Participation Complete TASCS number [TASCS ID].
Email Message: All subjects have been withdrawn from the study and no new patient charges should be generated on the protocol after [insert date].

IDS charges may continue if the study drug remains in the IDS Pharmacy.

All Subjects Withdrawn Correction

Trigger: when a date is changed or removed from the All Subjects Withdrawn Date field and saved.
Email Subject: All Subjects Withdrawn Date Change [TASCS ID]
Email Message: The date in the All Subjects Withdrawn Date field has been changed or deleted.

Additional PO Entered

Trigger: when a subsequent PO is entered and Save Changes is clicked.
Email Subject: TASCS Additional PO Entered [TASCS ID]
Email Message: The user has entered a new purchase order for this study. Update the billing account with the new information.

Biling Accounts

Trigger: when a new PO is entered and Save Changes is clicked.
Email Subject: TASCS Billing Accounts [TASCS ID]
Email Message: The user is requesting billing accounts for this study. Set up accounts needed based on the information in the Services screen.

Coverage Analysis Complete

Trigger: when Coverage Analysis Complete is checked and Save Changes is clicked.
Email Subject: TASCS Coverage Analysis Complete *[TASCS ID]*
Email Message: Fairview has completed the coverage analysis. A billing grid for this study is now available in the Report menu.

A signed billing grid is required with your IRB application.

IDE/HDE Alert

Trigger: when an IDE/HDE number is entered and Save Changes is clicked.
Email Subject: TASCS IDE/HDE Alert *[TASCS ID]*
Email Message: Please review the referenced protocol to determine if this is an IDE or HDE use. Work with the Protocol Contact to collect the information needed to submit the use to the local Medicare contractor (Noridian).

Modification Detail

Trigger: when Resubmit to Providers button is clicked.
Email Subject: Modification Detail for TASCS number *[TASCS ID]*.
Email Message: The user has made changes to the Services or Payers screens.

The Principal Investigator may need to revise the consent form (cost section, required visits or tests, etc.) based on these changes and notify the IRB accordingly.

The changes are as follows: [list the changes by field].

Patient Case Number

Trigger: when a case number is entered and Save Changes is clicked.
Email Subject: TASCS Patient Case Number *[TASCS ID]*
Email Message: A patient case number has been created for your subject [*Subject ID and initials*]. The patient case number is available on the Subjects screen in TASCS and will also appear on the Encounter forms you print for this subject.

Pricing

Trigger: when Pricing Complete is clicked
Email Subject: TASCS pricing *[TASCS ID]*
Email Message: Your price list for this study is ready to review. The Research Pricing report is available under the Report menu in TASCS.

Protocol Status Change

Trigger: When status is changed to Inactive.
Email Subject: TASCS Protocol Status Change *[TASCS ID]*
Email Message: Providers: The protocol status has been changed from active to inactive. Please ensure that all invoicing and collection activity is complete and inactive the billing accounts.

Protocol Status Correction

Trigger: When status is changed from Inactive to Active.
Email Subject: TASCS Protocol Status Correction *[TASCS ID]*
Email Message: Providers: Protocol has been re-activated. Please keep billing accounts open. If accounts were close and cannot be re-opened, advise Protocol or Billing Contact regarding necessary action to create new accounts.

Service Alert

Trigger: when Submit to Providers is clicked
Email Subject: TASCS Services Alert *[TASCS ID]*
Email Message: The user has submitted services for review and pricing.

Service Discrepancy Alert

Trigger: when a new service discrepancy is entered and Save Changes is clicked
Email Subject: TASCS Service discrepancy Alert *[TASCS ID]*
Email Message: The user has noted an additional service that occurred during a research visit. Please review the additional service to direct charges accordingly: [*list visit date, MRN and service description*].

Service Discrepancy Alert Correction

Trigger: when the Remove checkbox is checked and saved on the Service Discrepancy screen.
Email Subject: TASCS Service Discrepancy Alert Correction *[TASCS ID]*
Email Message: A service discrepancy was entered in error for [*insert visit date, MRN and service description*]. No additional services were used and no action is needed.

Services/Payers Modification

Trigger: when Unlock & Modify is clicked on either the Services or Payers screens
Email Subject: Services/Payer Modifications to TASCS *[TASCS ID]*
Email Message: The user has unlocked the Services or Payers screen to make changes. See the subsequent email titled “Modification Detail” for specific information about what changes were made.

No action is needed at this time.

Sponsor Change

Trigger: when the data in the Sponsor field is changed and saved.
Email Subject: TASCS Sponsor Change *[TASCS ID]*
Email Message: The sponsor has been changed for this study. Update the research pricing as needed.

Subcontract Alert

Trigger: when Subcontract is checked and Save Changes is clicked
Email Subject: TASCS Subcontract Alert *[TASCS ID]*
Email Message: The user is requesting a contract with Fairview or UMP. Please contact the user for more information.

Subject Consented

Trigger: when a new consent date is entered and Save Changes is clicked
Email Subject: TASCS subject consented *[TASCS ID]*
Email Message: A new subject has been consented for this study. The subject's information is as follows: [*list initials, MRN, Date of Birth and date of consent*].

UMP: Please assign a case number and enter into TASCS.
Fairview: Please flag the subject in the appropriate billing system(s).

Subject Consented Date Change

Trigger: when the consent date on the Subject Tracking Form is changed or deleted.
Email Subject: TASCS Subject Consent Date Change *[TASCS ID]*
Email Message: The date for subject consent was either changed or deleted. The subject's information is as follows: [*list initials, MRN, Date of Birth and date of consent*].

Subject Withdrawn

Trigger: when a date is entered into the Subject Withdrawn date field and saved.
Email Subject: Subject Withdrawn *[TASCS ID]*
Email Message: A subject has been withdrawn from this study. The subject's information is as follows: [*list initials, MRN, Date of Birth, and date of withdrawal*].

UMP: Please inactivate the patient case number.
Fairview: Please remove the patient flag from the billing system(s).

Subject Withdrawn Date Change

Trigger: when a date is changed or removed from the Subject Withdrawn date field and saved.
Email Subject: Subject Withdrawn Date Change *[TASCS ID]*
Email Message: The date for subject withdrawal was either changed or deleted. The subject's information is as follows: [*list initials, MRN, Date of Birth, and date of withdrawal*].

If the date was deleted, the subject continues to participate. If the date was changed, update the billing accounts accordingly.

Billing Contact Change

Trigger: when the name in the Billing Contact field is changed and saved.
Email Subject: Billing Contact Change *[TASCS ID]*
Email Message: The billing contact has been changed. Please update the billing files accordingly.

Short Title Change

Trigger: when information in the Short Protocol Title field is changed and saved.
Email Subject: Short Title Change [TASCS ID]
Email Message: The short titled has been changed. Please update the billing files accordingly.

Appendix D -Field Definition by screens

Protocol Entry

Field Name	Field Type	Field Definition
All Subjects Withdrawn Date	Autofill	Date the last subject enrolled (or to be enrolled) in the study has ended his/her participation – pulled from subject tracking form entry.
Amendment Amount	Number (7)	The amount (per the contract) that can be invoiced for processing the amendment.
Amendment Date	Month/Day/Year	The date of the protocol amendment.
Amendment Number	Number (2)	Used to record the number of protocol amendments.
Amendment Rec'd Date	Month/Day/Year	The date the protocol amendment was received.
Billing Contact	Drop down	Protocol business manager - the approver of protocol expenses commonly called administrator or accountant.
Certificate of Confidentiality	Check box	Indicates a Certificate of Confidentiality is in place
Chartfield1	Char (10)	Check with your department for correct financial system identification numbers. Enter placeholder until known.
Chartfield2	Char (10)	Check with your department for correct financial system identification numbers. Enter placeholder until known.
Check here if you need a new subcontract with Fairview or UMP	Check box	Check the box if you need to purchase labor from Fairview or UMP. Also applies to Professional Services Agreements (PSA) and Contracts for Professional Services (CPS). Please note that professional fees do not require a subcontract. Contact Fairview or UMP with questions.
ClinicalTrials.gov #	Char (11)	Clinical Trials.gov protocol unique identifier. ClinicalTrial.gov # is required of Service Provider when charges are billed Insurance. Effective 01/01/2014.
Comments	Char, any text	General comments and notes field to store any information useful to the management of the protocol or to communicate about the management of the protocol.
Contract #	Char (15)	Financial system number assigned to the contract for the protocol. Check with your department for how to find this number.
Contract Exception	Drop down	Used to indicate whether a contract remains open until all work is completed or has a firm end date.
Contract Signature Date	Month/Day/Year	Date that indicates contract has been executed by all parties (use the latest signature date).

Field Name	Field Type	Field Definition
Coverage Analysis Complete	Check box	Used to indicate to the researcher that Billing Grid Report is ready to be printed, signed by PI and submitted to IRB..
Coverage Analysis Complete Date	Autofill	Date populated by the system when the Coverage Analysis checkbox is checked for the first time.
CPRC Application to PI Date	Month/Day/Year	Date the completed CPRC application was given to the Investigator for review.
CPRC Approval Date	Month/Day/Year	Date on the CPRC final approval letter.
CPRC Number	Number (15)	Number assigned to the protocol by the Cancer Protocol Review Committee (CPRC).
CPRC Stipulation Date	Month/Day/Year	Date on the CPRC stipulation letter.
CPRC Stipulation Response	Month/Day/Year	Date the CPRC stipulation response is sent to the Investigator for review.
CPRC Submission Date	Month/Day/Year	Date the CPRC application was submitted to the committee.
CRO (Contract Research Org)	Drop down	Contract Research Organization - commonly employed by business and industry sponsors.
CRO Contact	Drop down	Contact person from contract research organization.
CTSI Application to PI Date	Month/Day/Year	Date the completed CTSI application was given to the Investigator for review.
CTSI Approval Date	Month/Day/Year	Date on the CTSI final approval letter.
CTSI Number	Number (5)	Number assigned to the protocol by the Clinical and Translational Science Institute (CTSI).
CTSI Stipulation Date	Month/Day/Year	Date on the CTSI stipulation letter.
CTSI Stipulation Response	Month/Day/Year	Date the CTSI stipulation letter is sent to the Investigator for review.
CTSI Submission Date	Month/Day/Year	Date the CTSI application was submitted to the committee.
DeptID	Drop down	Check with your department for correct financial system identification numbers.
EFS Fund	Char (4)	Check with your department for correct financial system identification numbers.
End Date	Month/Day/Year	Projected protocol End Date - enter date one year from protocol entry date until firm date is known (firm date should match SPA records).
End of Enrollment	Autofill	Date that enrollment in the protocol is closed – pulled from subject tracking form entry.
EPIC #	Autofill	Clinic account number - pulled from lab/account set-up entry screen
Estimated $/Subject	Autofill	Calculation: Total Value minus Start-Up divided by number of subjects.
Fin Emplid	Char (7)	Enter the Principal Investigator's employee ID number.
Final Monitoring Visit	Month/Day/Year	Date the sponsor performs the final monitoring visit and close-out activities.
Final Protocol Receipt Date	Month/Day/Year	Date final protocol was received.

Field Name	Field Type	Field Definition
First Contact Date	Month/Day/Year	Date site was first approached about the study.
First Subject Consent Date	Autofill	Date the first subject signed a consent form for the study - pulled from subject tracking form entry.
First Subject Enrolled Date	Autofill	Date the first subject completes one visit after consent - pulled from subject tracking form entry.
Flowcast Study #	Autofill	Flowcast study number - pulled from lab/account set-up entry screen.
Full Protocol Title	Char, any text	Full protocol title (to match IRB and SPA records).
Funder Approval Date	Month/Day/Year	Date the funder approves the budget for the protocol.
Hospital Account #	Autofill	Hospital account number - pulled from lab/account set-up entry screen.
Hospital Account #	Autofill	Additional hospital account number (if applicable) - pulled from lab/account set-up entry screen.
Humanitarian Device Exemption	Char (7)	The humanitarian device exemption (HDE) number assigned by the FDA
IDS#	Autofill	Investigational drug services account number - pulled from lab/account set-up entry screen.
Inactive Date		Year all work on the protocol was completed (or was rejected or declined) - inactivates the protocol in system.
Investigational Device Exemption	Char (7)	The investigational device exemption (IDE) number assigned by the FDA.
Investigational New Drug #	Char (10)	The investigational new drug (IND) number assigned by the Food and Drug Administration (FDA) If the test article is a biologic - enter the BLA number in this field.
Invoice for Amendments	Yes/No	Used to indicate whether or not the contract with the sponsor will provide payment for processing protocol amendments.
IRB Application to PI Date	Month/Day/Year	Date the application was given to the Investigator for review.
IRB Approval Letter Date	Month/Day/Year	Date on the final IRB approval letter.
IRB Approval Letter Rec'd Date	Month/Day/Year	Date final IRB approval letter is received.
IRB Continuing Review Date	Month/Day/Year	IRB end of approval date.
IRB Meeting Date	Month/Day/Year	Date the IRB will consider the application.
IRB Number	Char (10)	Code number used by IRB to identify protocol.
IRB Stipulation Date	Month/Day/Year	Date on the initial stipulations letter from the IRB.
IRB Stipulation Response Date	Month/Day/Year	Date the IRB stipulation response letter is delivered to the Investigator for review.
IRB Submission Date	Month/Day/Year	Date the IRB application was delivered to the IRB.
Lab #	Autofill	Lab account number - pulled from lab/account set-up entry screen.

Field Name	Field Type	Field Definition
Other Application to PI Date	Month/Day/Year	Date the application was given to the Investigator for review.
Other Approval Date	Month/Day/Year	Date on the final approval letter.
Other Scientific Review	Drop down	Select the scientific review option that applies.
Other Scientific Review Number	Number (10)	Number assigned to the protocol.
Other Stipulation Date	Month/Day/Year	Date on the stipulation letter.
Other Stipulation Response Date	Month/Day/Year	Date the response to stipulations letter is sent to the Investigator for review.
Other Submission Date	Month/Day/Year	Date the application was delivered to the committee.
No Services Check Box	Check box	Indicates no protocol services are needed from Fairview or UMP. Prevents auto-emails to providers and serves as a filter for various exception reports.
Payment for Screen Fails	Yes/No	Used to indicate whether or not the contract with the funder includes payment for subjects who are screened but cannot enroll .
PI	Drop down	Principal Investigator for the protocol.
Program	Char (5)	Check with your department for correct financial system identification numbers.
Project	Char (8)	Check with your department for correct financial system identification numbers.
Protocol Contact	Drop down	Protocol Contact responsible for direct-to-subject contact - commonly called the research coordinator.
Protocol Monitor	Drop down	Data monitor assigned to the protocol - person who reviews protocol compliance and data collection.
Radiation Committee Application to PI Date	Month/Day/Year	Date the completed radiation application was given to the investigator for review.
Radiation Committee Approval Date	Month/Day/Year	Date on the final radiation committee approval letter.
Radiation Committee Number	Char	Number assigned to the protocol by the radiation committee.
Radiation Committee Stipulation Date	Month/Day/Year	Date on the radiation committee stipulation letter.
Radiation Committee Stipulation Response	Month/Day/Year	Date the stipulation response is sent to the investigator for review.
Radiation Committee Submission Date	Month/Day/Year	Date the radiation application was submitted to the committee for review.
Short Protocol Title	Char (70)	Abbreviated protocol name - limited to 70 characters (may use acronyms).
SPA Contact	Autofill	SPA grant administrator working on the protocol.
Sponsor	Drop down	Choose the sponsor (the person or group that wrote the protocol). Each sponsor has a funding type associated: Business/Industry, Federal, State, University, Other (see Appendix B for definitions).

Field Name	Field Type	Field Definition
Sponsor Contact	Drop down	Name of sponsor contact.
Sponsor Protocol #	Char (11)	Sponsor assigned protocol unique identifier.
Start Date	Month/Day/Year	Protocol Start Date - enter date of protocol entry until firm date is known (firm date should match SPA records).
Startup Payment	Number (10)	Non-refundable start-up payment listed in the contract.
Status	Drop down	Select from drop down options: Active-Approved (ready to enroll); Active-In the Approval Process (work is in process - not ready to enroll); Active-Future Protocol (not working on the protocol yet); Inactive (completed); Inactive (rejected/declined).
Subjects Consented	Autofill	The number of subjects who have signed a consent form for the study - pulled from subject tracking entry.
Subjects Contracted	Number (4)	Total number of subjects estimated to be enrolled in the protocol (from contract, if applicable).
Subjects Enrolled	Autofill	The number of subjects who have signed a consent form for the study and have completed at least one more study visit - pulled from subject tracking form entry.
Subjects Withdrawn	Autofill	Total number of subjects withdrawn - pulled from subject tracking form entry.
TASCS #	Autofill	Sequentially assigned - 2 digits year; 4 digits protocol.
To Dean Date	Month/Day/Year	Date the final Proposal Routing Form and documents go to the Dean for signature.
Total Value	Number (10)	Total value of the contract if all subjects completed - (use number from Notice of Grant Award).
Total Field Count	94	

Visit Entry

Field Name	Field Type	Field Definition
Administrator Hours	Number	The number of hours budgeted for an employee to complete his/her work per subject at this milestone.
Check box if any medical/lab services needed	Check box	Check box if any medical/lab services will be needed from any Provider at the visit. See note on Visit Entry screen for definition of medical/lab services.
Contract amount	Number	The amount, according to the contract, the site will be paid for each subject completing this milestone.
Coordinator Hours	Number	The number of hours budgeted for an employee to complete his/her work per subject at this milestone.

Field Name	Field Type	Field Definition
Delete Box	Check box	The delete function will only work if there is no other saved data related to the visit (e.g., payers or visit dates).
Description	Char (14)	Label for each research subject encounter required by the protocol - i.e., Visit 1, Visit 2; Day 23 Phone Call. Visit names must be unique and must be listed in the order they will occur.
Order	Number	Order is assigned by TASCS, but visits can be added and the order changed as needed.
PI Hours	Number	The number of hours budgeted for the Investigator to complete his/her work per subject at this milestone.
Total Field Count	8	

Services Entry

Field Name	Field Type	Field Definition
Last Modified	Autofill	Date user last changed information in this row.
Medical/Lab Services	Char (65)	Enter the requested test/service - free text up to 65 characters.
Notes	Char, any text	General comments and notes field to store any information about the medical or lab services entered.
Service Location	Drop down	Choose the location at which service will be provided (UMMC Clinic, UMP Clinic, Fairview Clinic, Fairview Hospital, UMP Imaging Center, or Other). Services to be provided at multiple locations will have to be added to the Services Screen once for each service location.
Status	Dropdown	System displays status of each line (service) as active. User may change status to inactive to show that the service is not needed. Services may not be deleted; rather they should be inactivated. Inactive services will sort to the bottom of the screen.
Total Field Count	5	

Payers Entry

Field Name	Field Type	Field Definition
Notes	Autofill	General comments and notes field to store any information about the medical or lab services entered.

Payers by Visit

Field Name	Field Type	Field Definition
Location	Autofill	Lists the service location from the Payers screen
Service	Autofill	Lists the services from the Payers screen
Payer	Dropdown	Choose the payer at the visit for the listed services.

Payers by Service

Field Name	Field Type	Field Definition
Visit	Autofill	Lists the visits from the Payers screen
Payer	Dropdown	Choose the payer for the service at the listed visits.

Services List (Provider Only)

Field Name	Field Type	Field Definition
Discrepancy	Autofill	Alerts to new or modified service.
Fee Schedule	Drop down	Usual & Customary pricing (except IDS, Lab and UMP).
Notes	Autofill	Notes entered by the AHC User on the Services screen.
Service Location	Autofill	Directs to appropriate fee schedule.
Write-in Service Description	Autofill	Free text to ID requested service.

Service Provider Pricing Entry (Provider Only)

Field Name	Field Type	Field Definition
Alternate Price	Number	Manual price to override Calculated Price (e.g., special agreements).
Calculated Price	Autofill	System generated Gross x Research Rate.
Effective Date - only for alternate prices - normals will be from the annual chargemaster	Month/Day/Year	Service added after original pricing completed.
Gross Price	Autofill	Fee schedule price.
Research Rate	Autofill	NIH and other non-profit, or B&I (except lab, IDS and UMP).
System Service Description	Drop down	Verify active unique service ID, add associated services as needed.
Unique ID	Autofill	ID specific to fee schedule that locates unique service.

Total Field Count 7

Account/Lab Set-up Entry

Field Name	Field Type	Field Definition
Amount	Number	Enter the purchase order amount for lab/medical services to be purchased from partner service Provider (Fairview).
Effective Date	Month/Day/Year	Enter the purchase order effective date for lab/medical services to be purchased from partner service Provider (Fairview).
End Date	Month/Day/Year	Enter the purchase order expiration date for lab/medical services to be purchased from partner service Provider (Fairview). Estimated end date should be entered if end date is not defined.
EPIC #	Char, any text	EPIC account number.
Flowcast Study #	Char, any text	Flowcast account number.
Hospital Account #1	Char, any text	Hospital account number.
Hospital Account #2	Char, any text	Hospital account number (if obtaining services from more than one hospital more than one is needed)

Field Name	Field Type	Field Definition
Hospital Account #3	Char, any text	Hospital account number (if obtaining services from more than two hospitals).
IDS#	Char, any text	Investigational Drug Services protocol account number.
In-House Lab Centrifuge	Yes/No	If lab will centrifuge check "yes", if not check "no."
In-House Lab Centrifuge Temperature	Char (11)	If lab will centrifuge, enter temperature requirement.
In-House Lab Choose Result Report Method	Radio Button	Select one option for report method of labs processed by an in-house lab.
In-House Lab Fax Results Number	Char (15)	Enter the fax number if lab results will be faxed.
In-House Lab Other	Char, any text	Enter any other in-house laboratory instructions.
In-House Lab Processing Instructions	Char, any text	If lab will process - enter laboratory processing instructions.
In-House Lab Results Name/address for fax header	Char (100)	Enter the name and address to whom faxed lab results should be addressed.
In-House Lab Routine Protocol	Yes/No	If centrifuge and separation will be performed by the lab, check whether there is a special protocol.
In-House Lab Special Collection Instructions	Char, any text	Enter any special collection instructions for in-house lab specimen collection.
In-House Lab Special Protocol Instructions	Char, any text	If there is a special protocol, enter instructions here.
In-House Lab Specimen Processed by Investigator	Yes/No	Check whether the specimens will be centrifuged and separated by Investigator/staff.
In-House Lab Specimen Storage	Check boxes	Check specimen storage requirement.
In-House Lab Specimens Collected By	Check boxes	Check boxes for specimen collection.
In-House Laboratory Site(s)	Check boxes	Check all laboratory sites where in-house labs will be processed.
Lab #	Char, any text	Lab project account number.
Location of Services	Check boxes	Select all service locations at which the research services needed will be provided.
Outside Laboratory Address	Char, any text	If an outside or central lab will process specimens, and a lab manual is not available enter the address of the lab.
Outside Laboratory Collection Instructions	Char, any text	If an outside or central lab will process specimens, and a lab manual is not available, enter collection instructions.
Outside Laboratory Name	Char (50)	If an outside or central lab will process specimens, and a lab manual is not available, enter the name of the lab.
Outside Laboratory Phone	Char (15)	If an outside or central lab will process specimens, and a lab manual is not available enter the phone number of the lab.

Field Name	Field Type	Field Definition
Outside Laboratory Processing Instructions	Char, any text	If an outside or central lab will process specimens, and a lab manual is not available, enter processing instructions.
Outside Laboratory Send Out Instructions	Char, any text	If an outside or central lab will process specimens, and a lab manual is not available, enter send out instructions.
Purchase Order #	Char (11)	Enter the purchase order number for lab/medical services to be purchased from partner service Provider (Fairview).
Recruitment Posting Categories	Check boxes	If research project will be listed on Fairview's recruitment website, check all categories that apply.
Recruitment Posting Check Box	Check box	Check box if research project should NOT be posted on Fairview 's recruitment website..

Total Field Count 34

Subject Entry

Field Name	Field Type	Field Definition
Birthdates	Month/Day/Year	Enter research subject's date of birth.
Ethnicity	Drop down	Choose ethnicity category for research subject.
Gender	Radio Button	Choose research subject gender.
Medical Record #	Number (10)	Enter Fairview medical record number.
Patient Case Number	Number (6)	UMP enters the patient case number for each subject. This will occur after the AHC user enters the date the subject signed consent on the Subject Tracking Form Entry screen.
Race	Drop down	Choose race category for research subject.
Subject #	Char (10)	Study or researcher assigned number or other unique identification.
Subject Initials	Char, any text	Research subject initials.

Total Field Count 8

Subject Tracking Form

Field Name	Field Type	Field Definition
All Subjects Withdrawn Date	Month/Day/Year	Date the last subject enrolled (or to be enrolled) in the study has ended his/her participation. Populating this field results in the following: • No further data entry permitted on the Subject Tracking Form • No encounter forms can be generated for the study • Providers are notified that all subjects are completed/withdrawn.
End of Enrollment	Month/Day/Year	Date that enrollment in the protocol is closed. Field must be populated in order to enter date into "All Subjects Withdrawn Date" field. Data in this field will notify recruitment website to remove the recruitment posting.
Notes	Char, any text	Use this field to store/communicate information about recording subject visit dates – e.g. "Subject 101 completed study MRI on 8/13/08 but completed study visit on 8/15/08."

Track by Visit

Field Name	Field Type	Field Definition
Additional Services?	Drop down	Before a visit date can be entered as completed - the following question must be answered: Were additional services used at the visit (e.g., not planned for this visit and they were not pre-printed on the Encounter Form or Research Lab Slip)? If there were additional services, indicate by choosing "Yes." If there were no additional services, indicate by choosing "No."
Initials	Autofill	List the initials from Subject Tracking Form
S #	Autofill	List the subject # from Subject Tracking Form
Visit	Month/Day/Year	Enter the date the subject completed the study visit. In situations where services for a protocol visit are provided on more than one day (for instance, an MRI for the protocol is completed in advance of the clinic visit), choose and enter the date the protocol visit was completed.

Track by Subject

Field Name	Field Type	Field Definition
Additional Services?	Drop down	Before a visit date can be entered as completed - the following question must be answered: Were additional services used at the visit (e.g., not planned for this visit and they were not pre-printed on the Encounter Form or Research Lab Slip)? If there were additional services, indicate by choosing "Yes." If there were no additional services, indicate by choosing "No."
Subject #, Initial	Month/Day/Year	Enter the date the subject completed the study visit. In situations where services for a protocol visit are provided on more than one day (for instance, an MRI for the protocol is completed in advance of the clinic visit), choose and enter the date the protocol visit was completed.
Visit	Autofill	List the visits from Subject Tracking Form.

Specific Time Point	Description
Consent	Enter the date the subject signed the initial study consent form. This will generate an automatic e-mail to Providers to assign a patient case number to each subject, if applicable.
Date w/d	Enter the date the subject's participation in the study ends (no further data should be collected after this date).
Reason	Choose the most appropriate reason from the "withdrawal reason" drop down.

Service Discrepancy Entry

Field Name	Response	Field Definition
Added Service Payer	Drop down	Choose the payer for the additional service.
Service Description	Char (65)	Enter the added test/service - free text up to 65 characters.
Service Location	Drop down	Choose the location at which service was provided.
Subject Medical Record #	Autofill	Data pulled from the Subject Tracking Form for each "yes" answer.
Visit Date	Autofill	Data pulled from the Subject Tracking Form for each "yes" answer.
Visit Description	Autofill	Data pulled from the Subject Tracking Form for each "yes" answer.

Total Field Count 8

Appendix E -Policies

AHC

AHC's Clinical Research Budgeting and Billing Policy can be found at:
http://www.ctsi.umn.edu/about/working-us/rates-and-billing/tascs-policy

UMP

University of Minnesota Physicians

Title:	**Clinical Research Billing**
Policy:	University of Minnesota Physicians' (UMPhysicians) billing for clinical services, items or tests associated with a clinical research project is accurate and in compliance with federal regulations.
Compliance Standards:	1. UMPhysicians' billing practices are consistent with the University of Minnesota and Fairview Health Services' policies and procedures. The University of Minnesota promotes compliance with the federal regulations through its Clinical Research Budgeting and Billing Policy. Fairview Health Services facilitates compliance through its Research Billing Policy. 2. UMPhysicians shall not bill clinical services, items or tests to the federal government, other payers, or the research subject when the same clinical services are funded or reimbursed by the clinical research sponsor; UMPhysicians may bill for clinical services, items, or tests when the clinical research sponsor has agreed to pay for clinical services only if payers do not reimburse for such services. 3. To facilitate compliance with this requirement, UMPhysicians uses the University of Minnesota's research database known as the Time and Study Collection System (TASCS) to appropriately identify and track the services which are to be paid by the clinical research sponsor and those which may be billed to a payer or the research subject. UMPhysicians' is dependent on the research project's Principal Investigator or designee to enter accurate data into TASCS. In support of the Principal Investigator, UMPhysicians maintains service fee schedules in TASCS and determines correct patient code and pricing for service-related charges.
Definitions:	**Clinical Research:** For the purpose of this policy, "clinical research" is defined as a systematic investigation, including research development, testing and evaluation involving human subjects, their data, records or tissue and is designed to develop or contribute to generalizable knowledge. The policy does not apply to clinical research meeting the Institutional Review Board (IRB) criteria for exemption (per 45 CFR 46.101).
Effective Date:	September 1, 2008.
Approval:	Compliance and Risk Management Committee, August 19, 2008.
Contact:	Ann Peterson, Vice-President, Patient Business Services.

Fairview

Fairview's Policies can be found at:
http://www.fairview.org/Research/BusinessOperations/Policies/index.htm

Research Billing: http://www.fairview.org/Research/S_033232

Appendix F -Use of Encounter Forms, Lab Slip and UMP Case Numbers

https://secure.ahc.umn.edu/tascs/use_of_encounter_forms.pdf

Appendix G -TASCS Manual Changes

Changes by Date

Date	Changes
2015-11-12	Updated TASCS URL to https://secure.ahc.umn.edu/tascs from http://tascs.ahc.umn.edu.
2015-07-20	Updated text that references 3 business days to 72 hours for consistency with the Budgeting and Billing Policy.
2013-12-31	ClinicalTrial.gov requirement information added
2013-03-14	Removed references to IBC. Updated the Use of Encounterform to a link to the form.
2013-01-14	Recapture and update screenshots. Added TASCS Workflow. Updated Auto-Email list.
2012-06-14	Update Auto Email list. Updated Appendix A and D.
2012-06-08	Updated the screenshot for the Protocol Entry screen. Added the specification for the No Services checkbox to the How-To section.
2012-06-01	Added clarification on the use of Encounter Forms. Added a new Appendix G for the Use of Encounter Forms, Lab Slips and UMP Case Numbers.
2011-09-29	Replacing new PI, Sponsor, PC and BC forms with new Add/Remove Personnel or Sponsor form.
2011-09-02	Removed MRN placeholder (9999999999) language. Removed CoC autopopulation language. Updated the access request form in Appendix B.
2011-03-31	Update TASCS Access Request Form, Appendix B. Changed ORA to RIOP, p.5, p.12 and p.13.
2010-11-17	Updated SPA role and responsibility, p.12. Updated AHC Budgeting and Billing Policy – Procedure – step 1: to clarify what SPA needs on the PRF p.86.
2010-10-15	Simplified contact list. Updated Access form.
2010-9-23	Update TASCS training reference p.12.
2010-7-13	Updated provider contacts. Updated automatic email specifications.
2010-5-04	Added Fairview Research Operation Manager contact info.
2010-4-30	Added Short Title Change auto email description into Appendix D.
2010-04-06	Appendix C: Moved “Masonic Cancer Clinic” from UMP Clinic to UMMC Clinic
2010-03-22	Corrected Fairview contact phone # on page 35 (labeled 29) from 612.672.7637 to 612.672.6737.